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DEPARTMENT OF HOMELAND SECURITY

RIN 1615–AC33

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

Wage and Hour Division

29 CFR Part 503

[DOL Docket No. ETA–2018–0003]

RIN 1205–AB91

Modernizing Recruitment Requirements for the Temporary Employment of H–2B Foreign Workers in the United States

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security and Employment and Training Administration and Wage and Hour Division, Department of Labor.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security (DHS) and the Department of Labor (DOL) (collectively, the Departments), are jointly issuing this final rule to amend the regulations governing DOL's certification of nonagricultural labor or services to be performed by temporary foreign workers in H–2B nonimmigrant status (H–2B workers). Pursuant to Section 214(c)(1) of the Immigration and Nationality Act (INA), this certification serves as DHS's consultation with DOL regarding whether a qualified United States (U.S.) worker is available to fill the petitioning H–2B employer's job opportunity, and whether a foreign worker's employment in the job opportunity will adversely affect the wages or working conditions of similarly employed U.S. workers. This final rule modernizes and improves the labor market test that DOL uses to assess whether qualified U.S. workers are available by: Rescinding the requirement that an employer advertise its job opportunity in a print newspaper of general circulation in the area of intended employment, and expanding and enhancing DOL's electronic job registry to disseminate available job opportunities to the widest audience possible.

DATES: This final rule is effective December 16, 2019.

FOR FURTHER INFORMATION CONTACT: Regarding the Department of Homeland Security: Charles L. Nimick, Chief, Business and Foreign Workers Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Ave NW, Suite 1100, Washington, DC 20529–2120, telephone (202) 272–8377 (not a toll-free call). Regarding the Department of Labor: Thomas M. Dowd, Deputy Assistant Secretary, Employment and Training Administration, Department of Labor, Box #12–200, 200 Constitution Ave NW, Washington, DC 20210, telephone (202) 513–7350 (this is not a toll-free number). Regarding 29 CFR part 503: Mary Ziegler, Director, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, Department of Labor, 200 Constitution Avenue NW, Room S–3510, Washington, DC 20210; telephone (202) 693–0071 (this is not a toll-free number).

Individuals with hearing or speech impairments may access the telephone numbers above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Statutory and Regulatory Background

The Immigration and Nationality Act (INA), as amended by the Immigration Reform and Control Act of 1986 (IRCA), establishes the H–2B nonimmigrant visa classification for a nonagricultural temporary worker ''having a residence in a foreign country which he has no intention of abandoning who is coming temporarily to the United States to perform . . . temporary [nonagricultural] service or labor if unemployed persons capable of performing such service or labor cannot be found in this country.'' INA section 101(a)(15)(H)(ii)(b), 8 U.S.C. 1101(a)(15)(H)(ii)(b). Employers must petition DHS for classification of prospective temporary workers as H–2B nonimmigrants. INA section 214(c)(1), 8 U.S.C. 1184(c)(1). DHS must approve this petition before a beneficiary may be considered eligible for an H–2B visa. Finally, the INA requires that ''[t]he question of importing any alien as [an H–2B] nonimmigrant . . . in any specific case or specific cases shall be determined by [DHS],[1] after consultation with appropriate agencies of the Government.'' *Id.*

DHS regulations provide that an H–2B petition for temporary employment in the United States must be accompanied by an approved temporary labor certification (TLC) from DOL issued pursuant to regulations established at 20 CFR part 655. *See* 8 CFR 214.2(h)(6)(iii)(A), (C)–(E), (h)(6)(iv)(A); *see also* INA section 103(a)(6), 8 U.S.C. 1103(a)(6), INA section 214(c)(1), 8 U.S.C. 1184(c)(1). The TLC serves as DHS's consultation with DOL regarding whether: (i) A qualified U.S. worker is available to fill the petitioning H–2B employer's job opportunity, and (ii) whether a foreign worker's employment in the job opportunity will adversely affect the wages or working conditions of similarly employed U.S. workers. *See* INA section 214(c)(1), 8 U.S.C. 1184(c)(1); 8 CFR 214.2(h)(6)(iii)(A) and (D).

Through the application process set forth in these regulations, DOL acquires the information necessary to make these factual determinations, including whether there are sufficient qualified U.S. workers available to perform the nonagricultural labor or services for which an employer seeks H–2B certification. 20 CFR 655.1. To that end, the regulations require an employer seeking H–2B temporary labor certification to test the labor market by recruiting U.S. workers for the position(s) in which it intends to employ H–2B workers. *See, e.g.,* 20 CFR 655.16, 655.40 through 655.46. The

[1] As of March 1, 2003, in accordance with section 1517 of Title XV of the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, any reference to the Attorney General in a provision of the Immigration and Nationality Act describing functions which were transferred from the Attorney General or other Department of Justice official to the DHS by the HSA ''shall be deemed to refer to the Secretary'' of Homeland Security. *See* 6 U.S.C. 557 (2003) (codifying HSA, Title XV, sec. 1517); 6 U.S.C. 542 note; 8 U.S.C. 1551 note.

outcome of this labor market test forms the basis of DOL's determination, through consultation with DHS before DHS makes the final determination on an H–2B petition, as to whether there are sufficient qualified U.S. workers available to fill the employer's job opportunity.

The INA also authorizes DHS to impose appropriate remedies against an employer for a substantial failure to meet the terms and conditions of employing an H–2B nonimmigrant worker, or for a willful misrepresentation of a material fact in a petition for an H–2B nonimmigrant worker. INA section 214(c)(14)(A), 8 U.S.C. 1184(c)(14)(A). The INA expressly authorizes DHS to delegate certain enforcement authority to DOL. INA section 214(c)(14)(B), 8 U.S.C. 1184(c)(14)(B); *see also* INA section 103(a)(6), 8 U.S.C. 1103(a)(6). DHS has delegated its authority pursuant to INA section 214(c)(14)(B), 8 U.S.C. 1184(c)(14)(B) and INA section 103(a)(6), 1103(a)(6), to DOL. *See* DHS, Delegation of Authority to DOL under Section 214(c)(14)(A) of the Immigration and Nationality Act (Jan. 16, 2009); INA section 103(a)(6), 8 U.S.C. 1103(a)(6); 8 CFR 214.2(h)(6)(ix) (stating that DOL may investigate employers to enforce compliance with the conditions of, among other things, an H–2B petition and a DOL-approved TLC). Within DOL, this enforcement authority has been delegated to the Wage and Hour Division (WHD), and is governed by regulations at 29 CFR part 503.

B. Current Recruitment Requirements

Under the regulations currently in effect, an employer seeking H–2B workers generally initiates the temporary labor certification process by filing the following with DOL: (1) An *Application for Temporary Employment Certification,* Form ETA–9142B (H–2B application) and (2) a copy of the job order submitted concurrently to the State Workforce Agency (SWA) serving the area of intended employment; and other documentation supporting the H–2B application. 20 CFR 655.15(a). Absent limited exceptions, an employer must file a completed H–2B application no more than 90 days, but no fewer than 75 days, before it seeks to employ H–2B workers. 20 CFR 655.15(b).

An Office of Foreign Labor Certification (OFLC) Certifying Officer (CO) will review the H–2B application and job order for compliance with program requirements. 20 CFR 655.30. The SWA concurrently reviews the job order to confirm that the employer's job opportunity complies with applicable requirements and notifies the CO of any deficiencies within 6 business days of receipt of the job order. 20 CFR 655.16(b). If the H–2B application and job order meet all applicable requirements, the CO will issue a Notice of Acceptance (NOA) within 7 business days from the date the H–2B application was received. 20 CFR 655.33. The NOA authorizes the next step in the temporary labor certification process—the recruitment of U.S. workers—and specifies a date on which the employer must provide an initial written report of its recruitment efforts. *See* 20 CFR 655.33(b).

The NOA directs the SWA to place the job order into intrastate clearance and circulate a copy of the job order to other states listed as anticipated worksites and designated by the CO for interstate clearance, where the job orders must remain active until 21 days before the date of need as set forth in 20 CFR 655.40(c). *Id.* Where the occupation or industry is traditionally or customarily unionized, the NOA instructs the SWA to circulate a copy of the job order to the central office of the State Federation of Labor and the office(s) of local union(s) representing employees in the same or a substantially equivalent job classification in the geographic area(s) where work will be performed. *Id.* Additionally, the NOA specifies the recruitment steps that the employer must conduct, within 14 calendar days from the date the NOA is issued, to complete the labor market test, unless the CO instructs otherwise. *Id.* Upon receipt of the employer's initial recruitment report, the CO will make a final determination whether to grant, partially grant, or deny the employer's H–2B application, based on the criteria for certification set forth in 20 CFR 655.50–655.51.

Sections 655.40 through 655.48 outline the recruitment standards and procedures that the CO may order an employer to conduct. Under these regulations, an employer is generally required to: (1) Place two print advertisements in a newspaper of general circulation serving the area of intended employment, *see* 20 CFR 655.42; (2) contact U.S. workers the employer employed in the previous year to solicit their return, *see* 20 CFR 655.43; and (3) contact the bargaining unit, if one exists, to seek referrals of U.S. workers, or if a bargaining unit does not exist, post notice of the job opportunity at the place(s) of employment for at least 15 consecutive business days, *see* 20 CFR 655.45. If relevant to the occupation and area of intended employment, the CO may also direct the employer to provide written notice of the job opportunity to a community-based organization, as provided in 20 CFR 655.45(c). Both print newspaper advertisements and the notice of posting at the place(s) of employment must meet the minimum content requirements set forth in 20 CFR 655.41, and an employer must maintain documentation of all advertising and recruitment efforts in the event of an audit or other review, as required by 20 CFR 655.56.

Finally, the CO may direct an employer to conduct additional recruitment where the CO determines there is a likelihood that qualified U.S. workers will be available to fill the employer's job opportunity. 20 CFR 655.46(a). The regulation provides the CO with flexibility to select the appropriate methods of recruitment on a case-by-case basis to ensure an adequate test of the labor market and that U.S. workers are apprised of available job opportunities. 20 CFR 655.46(b) leaves to the CO's discretion the precise nature of the additional recruitment an employer may need to conduct, and provides a non-exclusive list of advertising options. The flexibilities contained in this regulatory provision permit the CO to keep pace with labor market trends and changes in technology that may affect how information about job opportunities is disseminated and how many U.S. workers search for and find jobs. Equally important, when assessing the appropriateness of a particular recruitment method, the CO considers all options at his or her disposal, including relying on the SWA's experience and expertise with local labor markets, and where appropriate, selects the appropriate methods of recruitment on a case-by-case basis.

C. Summary of Proposed Changes to the Recruitment Requirements and the Changes Adopted in This Final Rule

On November 9, 2018, the Departments issued a notice of proposed rulemaking (NPRM) announcing their intent to modernize the recruitment that an employer must conduct in conjunction with an H–2B application. *See* 83 FR 55977, 55979 (Nov. 9, 2018). Specifically, the Departments proposed to eliminate the general requirement that an employer advertise its job opportunity in a print newspaper and replace it with a requirement to post an electronic advertisement on a qualifying website. The Departments invited interested parties to submit written comments on all aspects of this proposal, including a variety of issues related to the electronic advertising requirement. The Departments specifically solicited comments as to

whether there were alternative methods of recruitment that would more broadly and effectively disseminate information about temporary nonagricultural job opportunities to U.S. workers. The Departments originally stated that they would accept comments through December 10, 2018, but in response to a request for an extension, they subsequently extended this period through December 28, 2018. The public may review all comments that the Departments received in response to the NPRM in the Federal Docket Management System (FDMS) at *http://www.regulations.gov,* docket number ETA–2018–0003.

Upon careful consideration of the comments received, the Departments have decided to adopt their proposal to transition to electronic advertising with several changes. Specifically, this final rule adopts the NPRM's proposal to eliminate the existing requirement for most employers seeking H–2B labor certification to advertise their job opportunities in print newspapers of general circulation in the area of intended employment. The Departments' transition to electronic advertising will not require an employer to place an electronic advertisement on the internet in the manner proposed in the NPRM. As explained in detail below, DOL will instead advertise all H–2B job opportunities by posting them on *SeasonalJobs.dol.gov*, the expanded and improved version of DOL's existing electronic job registry.

D. Joint Issuance of This Final Rule

In order to effectuate DHS's requirement for DOL consultation pursuant to 8 U.S.C. 1184(c)(1), which is provided in the form of temporary labor certifications, DOL must issue regulations to structure procedures and standards for its issuance of labor certifications, as DOL has done for almost 50 years. On April 29, 2015, following a court's vacatur of nearly all of DOL's H–2B regulations, the Departments jointly promulgated an interim final rule (IFR) governing DOL's role in issuing temporary labor certifications and in enforcing the statutory and regulatory rights and obligations applicable to employment under the H–2B program. *See* Temporary Non-Agricultural Employment of H–2B Aliens in the United States, 80 FR 24042 (Apr. 29, 2015) (''2015 H–2B IFR'').

As explained in the 2015 H–2B IFR, following conflicting legal decisions about DOL's authority to independently issue legislative rules to carry out its duties for the H–2B program under the INA, the Departments jointly issued the 2015 H–2B IFR to ensure that there can be no question about the authority for and validity of the regulations in this area. 80 FR at 24045; *see also* 80 FR at 24044–47.[2]

Specifically, DHS's participation in the rulemaking is pursuant to its broad authority to issue rules in the H–2B program under 8 U.S.C. 1103(a)(3) and 1184(a), and, as referenced above, DOL—which has the institutional expertise on all matters relating to the domestic labor market and has for decades issued temporary labor certifications and legislative rules governing them in the nonagricultural foreign worker program—is necessarily authorized to promulgate rules governing its issuance of temporary labor certifications pursuant to 8 U.S.C. 1184(c). *See also* 8 U.S.C. 1103(a). The Departments further explained in the 2015 H–2B IFR that by jointly issuing that rule, ''the Departments affirm that [it] is fully consistent with the INA and implementing DHS regulations and is vital to DHS's ability to faithfully implement the statutory labor protections attendant to the program.'' 80 FR at 24045–46. Litigation on these and related matters is ongoing. Accordingly, notwithstanding that DOL has the authority to independently issue this Final Rule, DHS is joining DOL in this rulemaking to ensure that there can be no question about the authority underlying this action.

E. Severability

To the extent that any portion of this final rule is declared invalid by a court, the Departments intend for all other parts of the final rule that are capable of operating in the absence of the specific portion that has been invalidated to remain in effect. Thus, even if a court decision invalidating a portion of this final rule results in a partial reversion to the current regulations or to the statutory language itself, the Departments intend that the rest of the final rule continues to operate, if at all possible, in tandem with the reverted provisions.

[2] The Departments' authority to jointly regulate has not been found invalid, and nothing otherwise precludes joint action in the H–2B program. While the same district court twice issued an injunction against DOL's unilaterally-issued H–2B rules, *see Bayou Lawn & Landscape Servs.* v. *Solis,* 2012 WL 12887385 (N.D. Fla. Apr. 26, 2012) and *Bayou Lawn* v. *Perez,* 81 F. Supp. 3d 1291, 1300 (N.D. Fla. 2014) (*Bayou II*), the court has since upheld the joint rules, *Bayou Lawn* v. *Johnson,* 173 F. Supp. 3d 1271, 1277, 1289–91 (N.D. Fla. 2016) (*Bayou III*), noting that the primary difference between the enjoined 2012 rules and the 2015 rules was their joint promulgation. *Id.* at 1277 n.2.

II. Revisions to 20 CFR Part 655, Subpart A

A. The Departments are Rescinding the Regulation Generally Requiring Employers to Place Print Newspaper Advertisements in the Area of Intended Employment

1. Background

In the NPRM, the Departments proposed to revise 20 CFR 655.42 to replace the requirement for an employer to place print newspaper advertisements with a requirement to post an electronic advertisement on a website that is widely viewed and appropriate for use by workers who are likely to apply for the job opportunity in the area of intended employment. The Departments based this proposal on data indicating that print newspaper circulation continues to decline and that U.S. workers are increasingly turning to the internet in their job searches. The Departments also relied on DOL's experience in administering temporary and permanent labor certification programs, as well as anecdotal evidence received from stakeholders, who reported that advertisements in print newspapers were not an effective means of recruiting prospective U.S. workers for temporary nonagricultural job opportunities. In light of this data, experience, and stakeholder feedback, the Departments asserted that classified advertisements in print editions were becoming a less effective means of recruiting U.S. workers, and proposed to replace 20 CFR 655.42's current requirement to place a print newspaper advertisement with a requirement to post an electronic advertisement on the internet.

Many of the H–2B employers and employer associations that submitted comments in response to the NPRM applauded the Departments' efforts to modernize the recruitment process and confirmed, based on their experience, print newspaper advertising is expensive and ineffective in attracting U.S. workers who are likely to apply for temporary nonagricultural job opportunities in most cases. For example, one commenter stated that most of the H–2B petitioner employers it represents ''almost never . . . receive U.S. applicants as a result of the print advertisements,'' and asserted, based on its experience, that print newspaper advertisements are not a meaningful source for recruiting workers for temporary nonagricultural job opportunities. Similarly, a commenter representing an employer stated it prefers to advertise electronically, on social media and online job boards,

because it never receives applications in response to print newspaper advertisements. Another commenter agreed that print advertising is ineffective and asserted that advertising costs are rising due to decreasing competition in the newspaper industry.

Nevertheless, a number of these commenters disagreed with the Departments' proposal to completely eliminate print newspaper advertisements. Some expressed concern that the proposed rule would have a significant adverse impact on the newspaper industry. One of these commenters acknowledged online advertising would be more effective but expressed concern only with the financial impact of the proposed rule.

One commenter associated with the newspaper industry asserted that the Departments' proposal to eliminate the print newspaper advertising requirement overlooked certain factors. This commenter stated that newspapers are more effective than the internet in disseminating information to relevant viewers. The same commenter also opined that many local newspapers reach a larger audience than their subscribership indicates because a single newspaper is read by multiple people, and the content in these newspapers is often available online. According to this commenter, the distribution and readership of a local newspaper, in all of its formats (print and electronic), can easily exceed the number of visits to a third-party job search website. Finally, this commenter maintained that newspapers play an essential role in placing electronic advertisements and noted that some newspapers use services that will not only post an employer's advertisement to large internet job boards, but also distribute the advertisements to other job search websites.

A number of commenters urged that the Departments provide an individual employer with the option to choose whether to post two print newspaper advertisements in accordance with the requirement in the existing rule or to post an electronic advertisement in accordance with the requirement in the proposed rule. These commenters provided varied reasons to justify their request. For instance, some were concerned about internet accessibility issues for employers. Others were concerned that mandating electronic advertisements would unfairly exclude U.S. workers who are uncomfortable with certain technology or live in areas without ready access to the internet. Some pointed to the studies cited in the NPRM as evidence that the Departments did not adequately consider whether online advertisements would be effective in reaching the types of U.S. workers who typically work in jobs filled by H–2B workers. One commenter asserted that the Departments' proposal would violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution because the Government would ''restrict access to potential jobs'' to people who have internet access.

Other commenters suggested that the Departments require employers to post advertisements both in print and electronic formats. Most of these commenters expressed general support for electronic advertising, but also noted that the Departments provided insufficient or incomplete evidence to demonstrate that electronic advertising would be any more effective in recruiting U.S. workers most likely to apply for temporary nonagricultural job opportunities. Some of these commenters expressed concerns that the Departments relied on information and data trends focusing on U.S. job seekers generally, and failed to consider more specific information regarding how job seekers located in rural communities and, more specifically, temporary nonagricultural workers obtain employment, as well as how employers recruit for temporary nonagricultural workers. These commenters cited data suggesting that many U.S. workers who might be interested in filling temporary nonagricultural job opportunities may not have reliable high speed internet access, which would impede U.S. workers from viewing and responding to advertisements for H–2B job opportunities.

Some commenters cited Pew Research Center data suggesting that the internet was used in job searches much less frequently by job seekers possessing less than a high school education, earning less than $30,000 per year, and residing in rural community areas, characteristics they asserted are often shared by workers in temporary nonagricultural employment.[3] A commenter representing a newspaper industry association cited a recent study conducted by the Federal Communications Commission (FCC) indicating that nearly 40 percent of Americans, or approximately 24 million people, living in rural areas lack access to fixed broadband internet service, 30 percent of rural Americans lack access to mobile LTE broadband, and cellular reception is generally poorer in these areas. Some of these commenters urged the Departments to engage in additional consultation with the stakeholder community and State Workforce Agencies, and conduct a more formal assessment of internet access and usage by U.S. workers most likely to apply for temporary nonagricultural jobs.

At times citing reasons similar to those who advocated for giving employers the option to use either method (for example, pointing to data suggesting that some workers still use print sources to search for jobs and may have limited access to the internet), some commenters generally questioned whether electronic advertisements alone would be effective in reaching U.S. workers interested in temporary nonagricultural employment. They suggested the dual requirement would ensure the broadest possible exposure to U.S. applicants. One commenter recommended leaving the print requirement in place until the new DOL platform discussed in the NPRM was fully operational, opining that the online advertising the NRPM described was unlikely to have sufficient oversight or consistency.

Finally, a commenter representing a newspaper industry association stated that electronic advertising would be less effective in recruiting temporary nonagricultural workers than the currently required newspaper advertisements. Citing the FCC report and the Pew Research Center report noted above, this commenter asserted that the proposed rule would make it more difficult for U.S. workers to apply for H–2B job opportunities because such jobs attract job seekers less likely to search for employment online, including those with a low income, low level of educational attainment, minorities, and job seekers residing in rural areas. The commenter stated that the Pew Research Center data showed rural Americans are less likely to use the internet to search for work than suburban or urban Americans. Despite these concerns, this commenter supported placement of advertisements on online job boards operated by newspapers or websites that partner with newspapers, such as *Careerbuilder.com* and *Monster.com,* but urged the Department to require both print and online advertising.

2. Discussion

After carefully considering the comments received, the Departments have decided to rescind 20 CFR 655.42. The regulations will no longer generally require a prospective H–2B employer to advertise its job opportunity in a newspaper serving the area of intended

[3] Aaron Smith, *Searching for Work in the Digital Era,* Pew Research Center, Nov. 19, 2015, *http://www.pewinternet.org/2015/11/19/searching-for-work-in-the-digital-era.*

employment. This decision is grounded in the Departments' determination that the newspaper advertisements required under this section do not generally contribute in a significant way to the labor market test that DOL administers to assess the availability of qualified U.S. workers, as compared to the electronic advertising as described in this rule.

This determination is supported by the lack of data indicating newspaper advertisements are an effective means of recruiting U.S. workers for temporary nonagricultural positions. Specifically, as noted in the NPRM, available data indicates that U.S. workers are now much more likely to turn to the internet to search for work, and classified advertisements in print newspaper editions are becoming a less effective means of notifying potential applicants about available job opportunities. *See* 83 FR 55877, 55979. The data available to the Departments and the supportive comments reviewed in preparation of this final rule lead DOL to conclude that electronic advertising is a more effective means of reaching U.S. workers seeking temporary nonagricultural job opportunities, and of achieving the goals of the H–2B labor certification program.[4] In addition, the Departments considered anecdotal accounts in comments from employers and employer associations, who reported that the newspaper advertisements they have placed in connection with this requirement have yielded very few, if any, applications from qualified U.S. workers.

In arriving at this determination, the Departments carefully considered the arguments that some commenters raised in support of retaining the requirement to place print newspaper advertisements. As explained below, however, none of these arguments contradict the findings discussed above that newspaper advertisements as a general requirement of prospective H–2B employers are a less effective means of recruiting U.S. workers for temporary nonagricultural positions. Accordingly, these arguments have not persuaded the Departments that the regulations must require every employer seeking H–2B workers to place print advertisements in order to effectively test the labor market for able, willing, qualified, and available U.S. workers. As is currently the case, to the extent DOL determines that an advertisement in a particular print publication is likely to reach qualified and available U.S. workers in specific areas or across certain populations, the CO retains the discretion to direct an employer to place such an advertisement on a case-by-case basis, under his or her authority to order additional positive recruitment. *See* 20 CFR 655.46.

Significantly, the commenters who urged the Departments to retain a general print newspaper-advertising requirement did not point to data that showed such advertisements are effective in recruiting U.S. workers for temporary nonagricultural positions. Rather, these commenters asserted advantages of newspaper advertisements in general terms or pointed to their importance in certain communities, compared to the advantage of electronic advertisements proposed in the NPRM, without specifically addressing the efficacy of requiring all prospective H–2B employers to post newspaper advertisements when recruiting U.S. workers for temporary or seasonal nonagricultural job opportunities. For instance, some commenters cited data indicating certain populations and demographics are less likely to use the internet when searching for jobs and one commenter asserted that Americans in some communities are more likely to turn to community newspapers than the internet to obtain local news and information. However, the referenced non-public data only purports to show newspaper readership; it does not address individual job search habits, so the conclusion drawn is not supported by the data on which it is based and the Departments are unable to determine whether it offers any useful information with respect to this rulemaking. The arguments that commenters raised regarding the circulation and distribution of newspapers similarly do not refute the Departments' observation in the NPRM that job seekers rarely learn about job opportunities using print newspaper advertisements, nor do the assertions and anecdotes received in response to the NPRM. Similarly, the fact that DOL can easily verify whether an employer has placed a newspaper advertisement is irrelevant to whether the placement of such advertisements is an effective means of testing the labor market.

The Departments acknowledge that the rates of internet access and use of the internet to search for job opportunities vary among cross-sections of the population based on factors like age, location of residence, income, education level, and ethnicity. However, as noted in the NPRM, data indicates that the internet is an increasingly popular method that job seekers among all demographics use most often and find most reliable. For example, the Pew Research Center report cited in the NPRM and by the newspaper industry commenter concluded that the internet ''is a near-universal resource among those who have looked for work recently.'' [5] The report noted that the data was ''based on the entire public—many of whom are retired, not in the job market, or have simply not had a reason to look for a job recently'' and while it is not possible to parse the data to determine precise rates of online job searching among all populations, it is clear that the internet is, by an increasing margin, the most widely used job search tool among job seekers across demographics. The Pew Research Center report ultimately found that when ''[n]arrowing the focus to the 34% of Americans who have actually looked for a new job in the last two years, fully 90% of these recent job seekers have ever used the internet to research jobs, and 84% have applied to a job online.'' [6] Importantly, while the Pew Research Center data indicates rural Americans are less likely to use the internet to search for job opportunities than urban or suburban Americans, the data does not support the conclusion that rural Americans are more likely to use print newspapers than the internet when searching for job opportunities.

Similarly, while the Departments also acknowledge that some job seekers may lack reliable access to advertisements on the internet, such access limitations are true of advertisements in any form, and the Departments believe the data supports the conclusion that electronic advertisements are currently, and will be increasingly, accessible to an overwhelming majority of job seekers across a much broader geographic area than print advertisements. The Departments understand the concerns of some commenters that job seekers,

[4] *See* Aaron Smith, *Searching for Work in the Digital Era,* Pew Research Center, Nov. 19, 2015, *http://www.pewinternet.org/2015/11/19/searching-forwork-in-the-digital-era* (only 32 percent of Americans use ''ads in print publications'' when searching for employment and only four percent found ads in print publications to be the most useful tool in obtaining their recent employment); Elaine C. Kamarck and Ashley Gabriele, *The News Today: Trends in Old and New Media,* The Brookings Institution (Nov. 10, 2015)(Stating there are now only 400 newspapers for every 100 million Americans, and that only 15 percent of Americans receive a daily newspaper). *https://www.brookings.edu/research/the-news-today-7-trends-in-old-and-new-media.*

[5] Aaron Smith, *Searching for Work in the Digital Era,* Pew Research Center, Nov. 19, 2015, *https://www.pewinternet.org/2015/11/19/1-the-internet-and-job-seeking/.*

[6] Aaron Smith, *Searching for Work in the Digital Era,* Pew Research Center, Nov. 19, 2015, *http://www.pewinternet.org/2015/11/19/searching-for-work-in-the-digital-era/.*

particularly in rural areas, are less likely to have access to reliable internet service. However, as noted in the FCC report cited by the newspaper industry association commenter, the number of Americans that lack access is declining, including Americans living in rural areas.[7] Importantly, while the FCC report indicated a number of rural areas still lag behind the rest of the country in access to fixed-site, terrestrial broadband internet, the report also noted that the number of Americans with access to broadband internet is much higher when additionally considering sources like satellite internet service providers and mobile LTE.[8] In contrast to increasing access to internet, the data cited in the NPRM shows that access to print newspapers continues to decline, there are now only 400 newspapers for every 100 million Americans, and only 15 percent of Americans receive a daily newspaper.[9] In addition, print newspaper advertisements are often accessible only to persons in the areas where that newspaper is circulated, while electronic advertisements can reach job seekers in a much larger geographic area.

The Departments agree that no single recruitment method will reach all job seekers and do not disagree with comments asserting that other forms of advertising, such as print newspaper advertisements, may be effective in some limited circumstances. The move to electronic advertisements—and to *SeasonalJobs.dol.gov* in particular—is simply one important step in the Departments' broader effort to modernize the H–2B program, which has for many years been hampered by the tools of another era. As explained further below, COs will retain their discretion under 20 CFR 655.46(a) to evaluate, on a case-by-case basis, whether additional recruitment is necessary to ensure an adequate test of the labor market for the employer's job opportunity. And, in some limited circumstances where newspaper print advertisements would be effective, the CO has the authority to direct such advertising.

Moreover, as discussed in detail below, the Departments have decided not to adopt the proposal to replace the requirement to place newspaper advertisements with a requirement for *an employer* to post an electronic advertisement on the internet. Instead, DOL will post an electronic advertisement on an employer's behalf on *SeasonalJobs.dol.gov,* an improved and expanded version of the electronic job registry that DOL is required to maintain under its existing regulations. *See* 20 CFR 655.34. This addresses concerns that some commenters expressed regarding the effect of the proposed rule on those employers who have limited or no access to the internet, because such employers will not need to access the internet in order to participate in the H–2B program. Accordingly, employers who lack access to the internet will not need to acquire access to the internet in order for *SeasonalJobs.dol.gov* to advertise their job opportunities or for them to respond to any applications received from U.S. workers in response to these advertisements. Likewise, employers will not need to determine whether a particular website meets applicable regulatory criteria or retain evidence of this posting. Rather, DOL will use information that an employer provides on its job order and H–2B application to generate the advertisement that DOL posts on the employer's behalf on *SeasonalJobs.dol.gov,* and U.S. workers interested in a particular job opportunity can apply to the employer directly using the contact information that the employer provided to DOL.

While the Departments are aware that the final rule may have an impact on members of the newspaper industry, the Departments are also obligated to carry out the statutory mandate in a manner that ensures the methods and locations in which employers conduct positive recruitment are effective. As a general requirement for all employers, the Departments have determined that newspaper advertisements do not generally contribute in a significant way to the labor market test, which must be carried out by prospective employers to determine the availability of able, willing, and qualified U.S. workers. Therefore, the impact the newspaper industry experiences as a result of this final rule, to the extent that it is relevant at all, is outweighed by the Departments' needs to more effectively carry out the statutory mandate to ensure an adequate test of the U.S. labor market.

The relevant question is whether this requirement is an effective component of the labor market test that DOL conducts in connection with an H–2B application. Given the absence of evidence suggesting print newspaper advertisements are comparably effective in recruiting U.S. workers for temporary or seasonal nonagricultural job opportunities, the Departments have decided not to continue requiring most employers seeking an H–2B labor certification to place print newspaper advertisements. Accordingly, DOL is rescinding 20 CFR 655.42, the regulation that generally requires employers to place such advertisements.

B. Instead of Requiring a Prospective H–2B Employer To Post Its Own Electronic Advertisement, as Originally Proposed, DOL Will Advertise the Employer's Job Opportunity on SeasonalJobs.dol.gov, an Improved and Expanded Version of the DOL's Electronic Job Registry

1. Background

In the NPRM, the Departments proposed to amend 20 CFR 655.42 to require that an employer post an advertisement on a website meeting certain criteria, namely a website that is widely viewed and appropriate for use by workers who are likely to apply for the job opportunity in the area of intended employment. The Departments suggested that such job search websites might include those that specialize in advertising job opportunities for the specific industry or occupation, and other classified advertisement websites with sections focused on local jobs. The Departments requested comments on whether they should establish additional qualifying criteria (*e.g.,* minimum number of unique visitors per month) or more specifically define the types of websites that an employer may use.

Under the Departments' proposed revision to 20 CFR 655.42, an employer's advertisement would need to be clearly visible on the website's homepage or easily retrievable using the search tools on the website, posted for a period of no less than 14 consecutive calendar days, and publicly accessible to U.S. workers at no cost using the latest browser technologies and mobile devices. The proposed rule also required employers to use commonly-

[7] Inquiry Concerning Deployment of Advanced Telecommunications Capability to All Americans in a Reasonable and Timely Fashion, GN Docket No. 17–199, FCC 18–10 (Feb. 2, 2018), *https://docs.fcc.gov/public/attachments/FCC-18-10A1.pdf* (''2018 Broadband Deployment Report'') (noting that between 2012 and 2016, mobile and fixed terrestrial broadband access was deployed to 43.4 million Americans and the number of Americans without mobile or fixed terrestrial broadband access fell from 72.1 million to 20.6 million. When taking into account fixed terrestrial, satellite, and mobile internet access, the report also notes that ''approximately 99.9 percent of Americans have access to one of these services, including 99.3 percent in rural areas and nearly all Americans in urban areas.'')

[8] 2018 Broadband Deployment Report at 26, 87 (stating 99.9 percent of all Americans and 99.3 percent of those in rural areas have access to either fixed broadband or mobile LTE, indicating 99 percent have access to mobile LTE and 95.6 percent have access to broadband at speeds of 25/3 Mbps).

[9] *See* Elaine C. Kamarck and Ashley Gabriele, *The News Today: 7 Trends in Old and New Media,* The Brookings Institution, Nov. 10, 2015, *https://www.brookings.edu/research/the-news-today-7-trends-in-old-and-new-media.*

understood terms and keywords to describe their job opportunities, so that U.S. workers likely to apply could easily retrieve advertisements using the website's search function. Moreover, in an attempt to ensure the advertisement would be readily available to U.S. workers at no cost, the proposed rule prohibited employers from placing it on a website that required U.S. workers to establish personal accounts or make payments of any kind to view the advertisement. For the same reason, the proposed rule also required the website to be functionally compatible with the latest commercial web browser platforms and easily viewable on mobile smartphones and similar portable devices. To ensure employers retained the documentation necessary to demonstrate their compliance with these requirements, the proposed rule required employers to print and retain screen shots of the web pages on which their advertisements appeared, as well as screen shots of the web pages establishing the path used to access their advertisements.

Separately, in the NPRM, the Departments provided notice that DOL was evaluating the development of a centralized online platform to automate the advertising of H–2B job opportunities in order to assist employers in complying with the proposed electronic advertising requirement. Specifically, DOL envisioned that this electronic advertising platform would maintain a standard set of data on each job opportunity for integration with a wide array of job search website technologies. As envisioned in the NPRM, employers who elected to use this electronic advertising platform would consent to have DOL transmit information about their H–2B job opportunities to companies offering to provide advertising services. These companies would, in turn, advertise the employers' job opportunities on their respective job search websites.

2. Discussion

The Departments received comments both in support and in opposition to the proposal to replace the print newspaper-advertising requirement in 20 CFR 655.42 with a requirement to post an electronic advertisement on the internet. Some commenters fully supported the Departments' proposed transition to electronic advertising, agreed it was a necessary modernization of the H–2B program, and expressed a belief that online advertisements would permit employers to recruit labor more quickly and reliably than print newspaper advertisements.

However, the Departments also received a number of comments that raised significant concerns with various aspects of the proposal. For instance, some commenters cited data indicating people in rural communities are less likely to have reliable high-speed internet access than those in urban areas, which could impede employers' ability to post—and U.S. workers' ability to view—electronic advertisements. These commenters raised concerns that workers in particular demographic groups, such as lower income workers or workers with low levels of education, are less likely to use the internet to search for job opportunities. Other commenters raised significant issues with the proposed criteria for websites, the minimum required duration of the posting, and the documentation that employers would be required to retain to establish compliance.

After considering these comments, the Departments continue to believe that electronic advertising is an effective medium through which to reach U.S. workers. However, upon further consideration of how an electronic posting requirement can be effective in testing the U.S. labor market, how it can be effectively administered and enforced, and by whom, the Departments have decided to rescind, rather than revise, the advertising requirement in 20 CFR 655.42. Instead, the Departments have decided that DOL will carry out the electronic advertising itself by posting H–2B job opportunities on *SeasonalJobs.dol.gov,* an improved and expanded version of the electronic job registry that DOL is required to maintain under its existing regulations. *See* 20 CFR 655.34. To accomplish this, in addition to placing copies of all approved H–2B job orders on its publicly accessible electronic job registry, 20 CFR 655.34, DOL will continue to enhance the functional capabilities of the registry so that it also serves as a job search website that broadly advertises and disseminates H–2B job opportunities to U.S. workers. As discussed in detail below, the Departments believe this approach strikes an appropriate balance between addressing the concerns that stakeholders have raised with the proposed electronic advertising requirement and realizing the Departments' goal of modernizing and improving the labor market test conducted in connection with an H–2B application.

Having DOL facilitate the electronic advertising of H–2B job opportunities will have several salutary effects. First, it addresses concerns raised in public comments regarding the effect that this rule will have on employers who lack internet access and/or who have religious objections to using the internet. The employer will not need internet access to advertise job opportunities because DOL will be placing advertisements on *SeasonalJobs.dol.gov* on behalf of all employers using the information that employers provide to DOL in their H–2B applications. U.S. workers interested in a particular job opportunity can apply by directly contacting the employer, using the contact information—regardless of whether that is an email or physical address—that the employer provided to DOL. Second, it eliminates the need to establish regulatory criteria for the websites on which employers may place advertisements or the documentation employers must retain to establish compliance with those criteria. It also reduces burden on prospective H–2B employers—who historically have been the parties tasked with placing advertisements—by effectively transferring the responsibility (and cost) for this activity from prospective H–2B employers to DOL. Finally, and most importantly, it strengthens the integrity and efficiency of the labor market test that is conducted in connection with an H–2B application by leveraging the latest job search technologies to more broadly disseminate information about H–2B job opportunities through a centralized website. The enhancements that DOL is making to its electronic H–2B job registry, as well as each of these salutary effects, are discussed in further detail below.

(a) DOL Will Improve and Expand Its Electronic H–2B Job Registry Instead of Creating a Separate DOL-Assisted Advertising Platform

As previously mentioned, after considering the comments received in response to the NPRM, the Departments have decided that the best approach is for DOL to assume the responsibility for posting an electronic advertisement through its own website. Accordingly, this final rule provides notice that DOL intends to continue to improve and enhance the electronic job registry that it maintains under its existing regulations. *See* 20 CFR 655.34 (generally requiring the CO to place a copy of an employer's job order on an electronic job registry once the employer's H–2B application has been accepted for processing, and generally requiring that this job order remain posted on the electronic job registry until 21 calendar days before the certified start date of work).

DOL initially implemented the job registry to accommodate the posting of H–2A job orders for two reasons. *See* 75 FR 6884, 6927 (Feb. 12, 2010) (2010 H–2A Final Rule). One was to promote public disclosure and transparency and the other was to have an additional tool through which U.S. workers and other intermediaries providing services to agricultural employers could more easily identify available job opportunities. DOL later expanded use of the job registry to include H–2B job orders to disseminate temporary nonagricultural job opportunities to the widest audience possible. *See* 80 FR at 24074. DOL has used the same technology platform to host its electronic job registry—the iCERT Visa Portal System (iCERT System)—since July 2010, shortly after § 655.144 as promulgated in its 2010 H–2A Final Rule went into effect.

Under the current H–2B program, once an employer's application has been accepted for processing, the CO will redact any confidential information on the employer's job order and upload a redacted image of the job order onto the iCERT System, where it will generally remain posted until 21 calendar days before the certified start date of work. *See* 20 CFR 655.40(c). At the conclusion of this period, the CO will change the job order to inactive status, so that the information on the job order will still be available for public research and access. The iCERT System currently allows the public to search and retrieve H–2B job orders using several common data points—including the H–2B application number, employer name, area of intended employment, work contract period, and job title. Stakeholder feedback suggests that many stakeholders value the transparency of a publicly available job registry and consistently use the current job registry to locate H–2B job orders.

Currently, however, the technology supporting the job registry is more than 10 years old, lacks compatibility with the latest mobile devices, and provides limited search options for the public to retrieve H–2B job orders. It also serves as a static repository of H–2B job orders and lacks functionality that can facilitate the dissemination of these job opportunities to the widest audience. Finally, the manual process of scanning, redacting, and uploading scanned images of job orders increases the risk of error, incomplete information, and delays in posting, especially during the winter months when employers are filing large numbers of applications for the upcoming spring and summer seasons.

To address these limitations and expand U.S. worker awareness and access to temporary and seasonal job opportunities, DOL is in the process of transitioning its electronic job registry to a new platform, *SeasonalJobs.dol.gov,* and it plans to decommission the public job registry on the iCERT System in the fall of 2019.[10] *SeasonalJobs.dol.gov* is a mobile-friendly website that leverages the latest technologies to automate the electronic advertising of H–2B job opportunities *and* ensures copies of H–2B job orders are promptly available for public examination.

SeasonalJobs.dol.gov is currently operational. Once a CO has accepted an employer's H–2B application for further processing, DOL posts a brief description of the employer's job opportunity on *SeasonalJobs.dol.gov* that includes a link to a full copy of the employer's job order. The employer's job opportunity appears on the website in a concise and easy-to-read format, using information that the employer reports to DOL on its H–2B application and job order. While currently functional, DOL continues to enhance the functionality of *SeasonalJobs.dol.gov* to make information about H–2B job opportunities more accessible to U.S. workers. For instance, the search options available in the iCERT System are limited to job title, employer name, job order posting date, and the state where work will be performed. Users will be able to create and save customizable job search profiles and request email notifications informing them when DOL posts positions that match their search criteria. In addition, a geolocation Application Programming Interface will connect a user's current geographic location (when available) to the website's automated search tool, so that search results favor job opportunities near the user's current location. Location history will also help DOL identify how many users are searching for work in certain areas of the country and more effectively steer H–2B job opportunities to groups of job seekers located in certain regional areas and/or seeking different types of temporary nonagricultural work.

In addition, *SeasonalJobs.dol.gov* will make information about H–2B job opportunities more accessible to U.S. workers with limited English proficiency by posting the jobs in a format that allows language translation services to access and translate both the general web content on *SeasonalJobs.dol.gov* and specific terms and conditions of the job opportunities presented on job orders through the site. It will also facilitate broader dissemination of available job opportunities by making a standard set of job data available to third-party job search websites, which will allow job search websites to execute web-scraping protocols that extract new H–2B job opportunities from *SeasonalJobs.dol.gov* and index them for advertising to U.S. workers. In fact, Jobs on Google and LinkedIn job search features index the H–2B job opportunities currently advertised on *SeasonalJobs.dol.gov,* and DOL is evaluating additional integrations with other commonly used job search and social media websites to cast as wide a net as possible to help Americans find jobs. Finally, DOL will be further enhancing the RSS feed capability to allow interested U.S. workers and stakeholders to tailor notifications of relevant job opportunities.

The Departments believe that the enhancements DOL has and will continue to make to the electronic job registry will improve the existing labor market test and resolve many of the concerns that commenters raised in response to the NPRM.

This approach is also consistent with suggestions that the Departments received from commenters who urged DOL to either allow postings on its electronic job registry to fulfill the proposed electronic advertisement requirement or to implement a DOL-assisted electronic advertising platform. In fact, most of these comments expressed support for a DOL-administered-advertising platform, noting it would reduce regulatory burdens on employers, assist employers in complying with advertising requirements, and enhance U.S. worker access to employers' job opportunities in a centralized location and standardized format. A labor union commenting on the proposal urged DOL to ensure that the platform would be compatible with smart phone technology, and that the platform provide notice of job opportunities to unions and worker advocacy organizations. It also urged the Departments to permit those organizations time to review the advertisements and provide input to DOL regarding the appropriateness of the occupational classification and designated prevailing wage. In contrast, one commenter believed it would be unnecessary for DOL to create a new or updated platform because it could use commercial applicant tracking systems

[10] DOL first announced that it would be launching *SeasonalJobs.dol.gov* on December 21, 2018. *See https://www.dol.gov/newsroom/releases/eta/eta20181221.*

that post advertisements to all of the major online job boards and permit applicants to complete applications at any time from any device.

The Departments have considered these comments, and while the Departments have decided not to go forward with the DOL-assisted advertising platform that was proposed in the NPRM, they anticipate that stakeholders will be pleased with the improvements DOL has—and continues—to make to the electronic job registry. DOL has administered this electronic job registry in some form for nearly a decade. Accordingly, employers have been and continue to be on notice that, as a condition of participating in the H–2B program, the CO will place a copy of their approved H–2B job order on an electronic job registry. As explained above, DOL created this job registry to promote greater public awareness of and access to H–2A and H–2B job opportunities. The enhancements DOL has made and continues to make to *SeasonalJobs.dol.gov*, including the capability for third-party websites to extract H–2B job opportunities for broader advertising, are designed to further this goal and increase the likelihood that U.S. workers interested in temporary nonagricultural opportunities, as well as intermediaries providing services to those workers, receive timely notice of H–2B job opportunities.

Because the Departments are not implementing a separate DOL-assisted advertising platform, but rather enhancing the electronic job registry that DOL is currently required to maintain, the Departments have decided that U.S. workers will be best served if DOL implements these enhancements as soon as practicable. Nevertheless, the Departments value all suggestions and ideas to improve the functionality of *SeasonalJobs.dol.gov* and invites public input on changes that DOL can make to attract U.S. workers who are likely to apply for seasonal or temporary nonagricultural jobs. To facilitate public input, DOL has made the site easily accessible and included a specific function to collect stakeholder feedback and questions. DOL will also continue—as is its practice—to solicit and incorporate informal feedback from program users and other stakeholders in the course of outreach and technical assistance activities (including DOL-hosted stakeholder meetings and webinars) and at conferences, forums, and events hosted by interested stakeholders.

The Departments have also considered issues that several commenters raised regarding technical difficulties with DOL's existing job registry and the iCERT System, and agree that it is critical for *SeasonalJobs.dol.gov* to function effectively and reliably. Although this is a goal of the Departments independent of public comments in response to the NPRM, the above-referenced steps that DOL is taking to meet this goal should address and allay the concerns of the stakeholder community.

(b) Posting H–2B Job Opportunities on *SeasonalJobs.dol.gov* Will Reduce Regulatory Burden and Address Concerns About the Proposed Criteria for Employer-Posted Electronic Advertisements

The Departments received numerous comments addressing electronic advertisements, the criteria that would apply to these advertisements, and the documentation that an employer would be required to maintain. Many commenters generally agreed with the Departments' proposal to transition to electronic advertising, but a number of commenters urged the Departments to modify the proposal in various ways. For example, several commenters expressed concern that the proposed rule did not accommodate employers who had limited or no access to the internet, and they urged the Departments to provide employers the option of posting an electronic advertisement *or* print newspaper advertisements.

The Departments also received many comments suggesting that the standard they proposed to define the websites on which an employer could place an electronic advertisement required clarification. A number of commenters felt the proposed standard was ambiguous and did not sufficiently identify the websites—or types of websites—that would be permissible under the proposed rule. One commenter explained that the approach announced in the NPRM was ''unworkable and unpredictable,'' given the sheer number of websites that would qualify under the proposed standard. These commenters expressed varying opinions about the types of websites they believed should qualify and, for differing reasons, urged the Departments to further clarify, define, or list the websites where it would be appropriate for an employer to advertise an H–2B job opportunity. For example, several commenters suggested the Departments should require advertising on specific websites, including social media websites, state and county employment websites, and the National Labor Exchange, an online advertising platform operated by SWAs in partnership with operators of private online job boards.

Other commenters, by contrast, opposed the adoption of more specific qualifying criteria, which they argued would be cumbersome and make the regulation difficult to adapt to future changes in practices and technologies. Indeed, at least one commenter expressed concern that the proposed standard would require employers to monitor website platforms and technologies to ensure that they remain compliant with regulatory criteria.

The Departments also received comments from stakeholders on whether the final rule should exclude advertisements placed on websites operated by employers or the employer-client of a job contractor. An association of attorneys and legal professionals, as well as several labor unions, asserted that placement of advertisements on websites operated by employers is insufficient to satisfy an employer's recruitment obligations. One commenter expressed concern that such advertising would require potential applicants to know that a specific employer is seeking to hire H–2B workers and permit unscrupulous employers to ''hide'' advertisements. A few of these commenters believed that employers should be required to post job advertisements on their websites as a supplement to advertisements on other websites, but did not believe advertising on these websites alone would be effective. In contrast, a commenter representing an employer association believed advertising on employer websites would be effective because these websites would be appropriate to both the industry and location of the job opportunity.

In addition, some commenters sought clarification on the documentation that an employer would be required to retain under the proposed recordkeeping requirements. For example, one commenter expressed concern that the proposed rule did not clearly articulate what documentation an employer must retain. Another commenter suggested it would be overly burdensome to print and retain screen shots documenting compliance with this rule and suggested an employer's attestation should be sufficient to verify compliance. A labor union urged the Departments to require employers to include in their recruitment reports both the advertisements and the documentation of advertising. Another commenter believed the proposed screenshot documentation method was outdated, but did not suggest an alternative. Finally, commenters associated with the

newspaper industry additionally alleged that newspapers are a more reliable means of documenting compliance, because they are archived and available if an employer loses its copy of the tear sheet, whereas screen shots of websites can be easily lost, altered, or fabricated.

The issues that these commenters raised have persuaded the Departments that it would be unduly difficult at this time to develop, interpret, and implement qualifying criteria to govern the types of websites on which employers should place an electronic advertisement, as well as the documentation that an employer should retain to demonstrate compliance with this requirement. In addition, it is unnecessary to impose such requirements upon employers, when DOL has the capacity to produce similar benefits through its own website. Accordingly, as explained above, the Departments have decided not to adopt their proposal to require that an employer post an electronic advertisement. Instead, DOL will advertise on an employer's behalf by posting its job opportunity on *SeasonalJobs.dol.gov.*

Assuming control over the posting of the electronic advertisement and placing it on a centralized, DOL-administered platform addresses many, if not all, of the above-referenced concerns. As a preliminary matter, the Departments will no longer need to establish—and employers will no longer need to comply with—regulatory criteria limiting the types of websites on which employers must place an electronic advertisement or the documentation necessary to demonstrate compliance with this requirement. Moreover, the advertisement that DOL posts on *SeasonalJobs.dol.gov* will not create any additional regulatory burden for an employer because the employer will have already provided DOL with information about its job opportunity on its job order and H–2B application, which DOL will use to generate the advertisement it posts on *SeasonalJobs.dol.gov.* U.S. workers interested in a particular job opportunity can apply by directly contacting the employer, using the contact information that the employer provided on its job order and H–2B application. As noted above, employers who lack access to the internet will not need to acquire access to the internet to post advertisements on *SeasonalJobs.dol.gov* or respond to any applications that they receive from U.S. workers in response to these advertisements, and employers will not need to determine whether a particular website meets applicable regulatory criteria or retain evidence of this posting.

Finally, the Departments believe this approach leaves unscrupulous employers no leeway to ''hide'' their job opportunities on websites that they suspect are unlikely to attract qualified and available U.S. workers. *SeasonalJobs.dol.gov* will offer U.S. workers a free, publicly accessible, and easy-to-use job search platform that identifies all job opportunities for which employers are seeking to hire H–2B workers.

Thus, the Departments' revisions to the labor market test in this final rule seeks to reduce the burden of applying for an H–2B labor certification, while simultaneously broadening the dissemination of all H–2B job opportunities in a more uniform format through a modernized technology platform.

(c) The Advertisements That DOL Places on *SeasonalJobs.dol.gov* Will Improve the Information That U.S. workers Receive About H–2B Job Opportunities

The Departments also received several comments questioning whether U.S. workers would be able—or likely—to access the electronic advertisements required under the proposed rule. In addition to concerns over issues of internet accessibility, explained elsewhere, commenters expressed concerns that U.S. workers would encounter difficulty determining where to look for information about potential job opportunities. A labor union, for example, stated that it would be difficult for job seekers to know where to look for advertisements because a vast number of websites might be appropriate under the criteria proposed in the NPRM. As explained below, the Departments' decision for DOL to assume control over the posting of the electronic advertisement not only reduces the burden of applying for an H–2B labor certification, but also improves worker access to information about H–2B job opportunities.

First, it ensures that all H–2B job opportunities are advertised in a centralized location and in a uniform manner. This eliminates the concern raised by some commenters that U.S. workers would not know where to go to look for information about available H–2B job opportunities if employers were not posting advertisements in consistent locations or that unscrupulous employers could intentionally post advertisements on websites that are unlikely to yield applications from able, willing, and qualified U.S. workers.

Second, DOL can assure broader dissemination of H–2B job opportunities without requiring an employer to ensure that the website on which it places its advertisement is functionally compatible with the latest commercial web browser platforms and easily viewable on mobile smartphones and similar portable devices. Under the Departments' approach, it is DOL (and not the employer) who will ensure compliance with these requirements. DOL will stay abreast of broader changes in technologies and implement appropriate upgrades to the usability and security of the *SeasonalJobs.dol.gov.* For example, unlike the iCERT System, *SeasonalJobs.dol.gov* uses Responsive Web Design (RWD), which allows DOL to optimize the design and content structure of the website to fit on the screen of the user's computer, smartphone, or other similar portable device, regardless of size. The RWD approach allows DOL to create a single website design that can reach users across a wide array of computing devices. DOL continuously tests the site's mobile device compatibility using a series of emulation tools and a wide array of actual mobile devices.

Third, DOL will be able to improve the presentation of H–2B job opportunities to U.S. workers. While the Departments continue to believe that U.S. workers should have access to all of the information that is currently required by 20 CFR 655.41, they also understand that, in some situations, a concise summary of the job opportunity may be more attractive to U.S. workers, at least as a starting point. Accordingly, the advertisements that DOL places on *SeasonalJobs.dol.gov* provide a concise summary of the job opportunity, highlighting select information about an employer's job opportunity and including a link to the job order, so that U.S. workers can quickly review listings to assess whether they are interested in a particular job and, if interested, review the job order to access all of the terms and conditions of employment. Additionally, DOL intends to upgrade *SeasonalJobs.dol.gov* to allow users to create and manage customizable notifications for the H–2B job opportunities. Specifically, as noted above, DOL plans to enhance the site's current RSS feed capability, which includes a basic function that alerts users when DOL updates web-based content, with more sophisticated options that will allow users to personalize these alerts so that they only receive notifications of new postings for specific types of temporary or seasonal

work and/or in predetermined frequencies (*e.g.,* immediately, daily, weekly, monthly) tailored to their individual preferences. Users will be able to manage these notifications and turn them off when they are no longer needed or relevant.

Fourth, DOL will be able to improve the accessibility of electronic advertisements to U.S. workers, especially those workers with limited English proficiency. The internet offers an abundance of content presented in languages other than English, and the Departments recognize there are already a number of free browser applications and extension technologies (*e.g.,* Google Translate, Chrome Duolingo, Firefox's Flagfox) that provide users with translations, definitions, and other language assistance. To assist U.S. workers who search for jobs online but who have limited proficiency in English, jobs available on *SeasonalJobs.dol.gov* will be posted in a format that allows language translation services to access and translate both the general web content and specific terms and conditions of the job opportunities presented on job orders. DOL is further evaluating whether existing technologies and services can provide effective language translation services, and can be implemented through the site, to both general web content on *SeasonalJobs.dol.gov* and specific information about H–2B job opportunities presented on the site. The Departments understand the challenges (*e.g.,* numerous language dialects, accurately applying grammatical rules) associated with language translation tools and services, but believe that it is important for the information on *SeasonalJobs.dol.gov* to be accessible and understandable to the widest possible audience of U.S. workers who are looking for employment. DOL will therefore work as expeditiously as possible within existing budgetary constraints to implement additional built-in language translation services for all job opportunities advertised on *SeasonalJobs.dol.gov.*

Finally, the Departments acknowledge that some U.S. workers may lack reliable access to the internet and agree that no single recruitment method will reach all job seekers. The Departments likewise do not dispute that other methods of recruitment may be effective in limited circumstances. Nevertheless, the Departments' move to electronic advertising—and to *SeasonalJobs.dol.gov* in particular—is only one aspect of the labor market test conducted in connection with an H–2B application. The existing labor market test additionally includes the intrastate and interstate clearance process administered by the SWA, *see* 20 CFR 655.16(c), the requirement for an employer to contact former U.S. employees, *see* 20 CFR 655.43, the requirement to post notice of the job opportunity at the worksite, and, in certain circumstances, provide written notice of the job opportunity to a community-based organization, *see* 20 CFR 655.45.

The Departments believe that the enhancements DOL has and continues to make to the electronic job registry will improve the existing labor market test by increasing awareness of H–2B job opportunities, which interested parties may then share with U.S. workers who do not have access to the internet or who may not use the internet to search for job opportunities. Moreover, as discussed in detail below, this final rule retains the option for DOL to require additional recruitment where the CO has determined that there is a likelihood there are qualified U.S. workers who will be available for the work, including where the job opportunity is located in an Area of Substantial Unemployment. *See* 20 CFR 655.46. Accordingly, even if certain U.S. workers interested in temporary nonagricultural jobs are unlikely to view an advertisement on *SeasonalJobs.dol.gov* (*e.g.,* workers who do not have internet access or who are otherwise unlikely to turn to the internet to search for available job opportunities), they may be identified through other steps in this labor market test.

C. The Departments Are Retaining the Options To Require Additional Employer-Conducted Recruitment Under § 655.46.

In developing this final rule, the Departments have given careful consideration to the responses they received in response to their request for comments regarding whether there are alternative methods of recruitment that would more broadly and effectively disseminate information about available job opportunities to U.S. workers. A number of commenters suggested other methods of recruitment, such as placing advertisements on radio stations, making use of 24/7 job hotlines, and placing advertisements in community-based or other publications that target populations who may be interested in temporary or seasonal work.

Two commenters representing worker advocacy organizations also urged the Departments to require more dissemination of H–2B job opportunities to unemployed U.S. workers through DOL-funded grantees under the Workforce Innovation and Opportunity Act and expand union notification requirements to those unions representing workers in the job opportunity on a nationwide scale. These commenters also recommended that the Departments expand the recruitment activities of the SWAs to ensure job seekers, particularly those who lack adequate access to the internet, are made aware of H–2B job opportunities. Specifically, one of these commenters suggested the Departments require the SWAs to consult with worker advocacy organizations to develop annual plans for recruiting U.S. workers on a nationwide scale targeting specific groups of unemployed U.S. workers using a variety of advertising methods.

Some commenters were not opposed to the idea of internet advertising, but suggested strengthening the requirements in the rule, maintaining that a single advertisement would not account for the broad range of positions and geographic areas where H–2B workers are employed. They urged the Departments to require employers to further tailor their recruitment. One commenter asserted that modern-day recruitment of hourly workers demanded a targeted marketing strategy such as a 24/7 job hotline and applicant tracking system. Another argued for leaving the specific methods of recruitment to the SWAs, who could develop recruitment plans suited to the needs of each locality. Another thought it ''critically important'' that the CO maintain flexibility to require additional advertising in certain circumstances. This commenter also recommended that, in addition to any electronic means for applying to jobs, there should also be a variety of non-electronic means, to account for the possibility that a U.S. worker will have limited or only short-term access to the internet.

The Departments appreciate the ideas and suggestions that they received on alternative forms of recruitment. DOL has considered each of these suggestions but notes that many of these proposals—including advertising on local radio stations or in community-based and ethnic publications or using commercial recruitment services—are challenging to regulate and monitor. Because the Departments do not currently have sufficient information regarding the efficacy of these proposals in recruiting U.S. workers for temporary nonagricultural employment, the Departments have decided that a generally applicable requirement for every employer to use these methods is unwarranted at this time. However, to the extent that DOL receives information indicating that one or more

of these methods are effective in a particular area or among specific groups of U.S. workers, the CO retains the authority under 20 CFR 655.46 to order an employer to use that method to recruit U.S. workers.

The Departments continue to believe that this provision provides sufficient flexibility to design recruitment procedures—and the appropriate means of recruitment in those areas—on a case-by-case basis taking into account the occupation and current labor market conditions. This provision provides the CO with flexibility to keep pace with the ever-changing labor market trends and technologies and select the most appropriate method(s) of recruitment for a particular job opportunity. The Departments' intention in requiring additional recruitment under this provision, including in areas of substantial unemployment (ASU), is predicated on the belief that more recruitment will result in more opportunities for U.S. workers. ASUs by their nature have a higher likelihood of worker availability; DOL's recognition of worker availability in these areas is a strong indicator that these open job opportunities may have more receptive potential populations.

Under 20 CFR 655.46 the CO has discretion to evaluate, on a case-by-case basis, the appropriate locations and methods of recruiting where there may be qualified U.S. workers available for job opportunities. The types of additional recruitment the CO may require the employer to conduct include print advertising, advertising on the employer's or another website, and contacting community and faith-based organizations. Title 20 CFR 655.46 does not afford the CO unlimited discretion; rather, it authorizes the CO to order only the recruitment necessary to ensure an adequate test of the labor market for the employer's job opportunity.

In determining whether and what additional recruitment is required for a position, the CO will continue to consider, among other information, information that DOL obtains from SWAs who are familiar with current labor market conditions and positioned to provide advice about the effective methods of recruiting U.S. workers for the job opportunity. The Departments acknowledge the comments they received suggested a wide array of alternative methods of advertising that, depending on the information provided to the CO, may effectively disseminate information about available job opportunities to U.S. workers. For example, based on the information DOL receives from SWAs, the CO may determine that a particular method of advertising (*e.g.,* a community-based newspaper) covering a regional area may be effective in recruiting U.S. workers for a particular position, in a specific location, during certain periods of the year, or in response to local or regional events like natural disasters, layoffs, and plant closures. In requiring the use of a particular method of advertising, the CO will take into consideration all available information about whether that method has been, or is likely to be, effective in generating referrals of qualified U.S. workers.

D. Other Technical Amendments Related to the Final Rule

This final rule also makes technical amendments to several regulatory provisions to ensure they conform with the substantive changes to the recruitment process discussed above. First, the rule amends 20 CFR 655.19(e)(1), 655.40(b), and 655.41(a) by replacing references to 20 CFR 655.42 with references to 20 CFR 655.43 to reflect the Departments' decision to eliminate the requirement for all employers to place print newspaper advertisements. For the same purpose, the final rule amends 20 CFR 655.56 by eliminating paragraph (c)(2)(ii), which references 20 CFR 655.42, and redesignating paragraphs (c)(2)(iii), (iv), and (v) as paragraphs (c)(2)(ii), (iii), and (iv), respectively. The final rule also amends 20 CFR 655.71 by removing the reference to ''newspapers and other publications'' to clarify that the CO has the discretion to order advertising in sources like newspapers and other publications, but 20 CFR 655.71(c) does not require the CO to order advertising in these sources.

Finally, the final rule also makes a minor technical revision to WHD regulations at 29 CFR part 503 to ensure they conform with the substantive changes to the recruitment process discussed above. Specifically, the final rule eliminates 29 CFR 503.17(c)(2)(ii), which includes reference to 20 CFR 655.41 and 655.42, and redesignates paragraphs (c)(2)(iii), (iv), and (v) as (c)(2)(ii), (iii), and (iv), respectively.

E. Out of Scope Comments on the Proposed Rule

The Departments received comments on several issues that were unrelated to their proposal to modernize the recruitment that an employer must conduct under the regulations by replacing print newspaper advertisements with electronic advertisements posted on the internet. The Departments recognize and appreciate the value of these comments and suggestions. However, they are outside the scope of this rulemaking and the Departments cannot adopt them without additional regulatory—and in some cases Congressional—action.

II. Administrative Information

A. Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

Under Executive Order (E.O.) 12866, the Office of Management and Budget (OMB)'s Office of Information and Regulatory Affairs determines whether a regulatory action is significant and, therefore, subject to the requirements of the E.O. and review by OMB. *See* 58 FR 51735 (Oct. 4, 1993). Section 3(f) of E.O. 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule that: (1) Has an annual effect on the economy of $100 million or more, or adversely affects in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as economically significant); (2) creates serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. *Id.* OMB has determined that this final rule is a significant, but not economically significant, regulatory action under Sec. 3(f) of E.O. 12866. Consequently, OMB has reviewed this rule.

E.O. 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; the regulation is tailored to impose the least burden on society, consistent with achieving the regulatory objectives; and in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. E.O. 13563 recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

This final rule is an E.O. 13771 deregulatory action because the cost savings to H–2B employers associated with the rule are larger than the costs.

The estimated cost savings associated with this regulatory action are derived from the rescission of § 655.42 to remove the newspaper advertising requirement, and the revision of § 655.56 to eliminate document retention requirements associated with print newspaper advertisements.

1. Discussion of Comments

In response to the NPRM, which instituted an online advertising requirement in place of the current print advertising requirement, some commenters took issue with the Departments' assumption that the cost savings of the proposed rule outweighed its costs. One commenter stated that the analysis did not attempt to estimate what burdens the proposed rule or any alternative rules considered would impose on U.S. workers, relative to the current rule, in terms of their ability to search for and locate available jobs. Another commenter suggested that the Departments' estimates for the costs of online advertisements underestimated actual fees, stating that prices for advertising online are in some instances the same as, if not greater than, the cost of a single newspaper advertisement. The same commenter believed the proposed rule's use of advertising rates for the largest newspapers in the five states with the most H–2B temporary labor certifications inflated the NPRM's estimated costs. The commenter stated that the proposed rule's analysis did not specify the criteria used for developing the cost estimates and was not representative of the smaller newspapers employers may use to meet print advertising requirements, noting that print advertising costs vary based on a number of factors (*e.g.,* advertisement size, number of lines, and geographic location). Additionally, the commenter asserted that the analysis inflated cost estimates because it failed to account for the fact that the advertising fee charged by many newspapers includes both digital and print advertising. Finally, the commenter asserted the analysis failed to account for the costs of compliance with the proposed rule for employers and the costs associated with DOL enforcement of the rule.

The proposed rule based the cost estimates for two newspaper advertisements on advertising costs from newspapers with the widest circulation in the five states where H–2B certifications are most prevalent, as well as the advertising costs from the most widely circulating newspapers in the top feeder states that are adjacent to the primary H–2B prevalent states. The estimate of $1,606.16 represents, on average, a reasonable estimate of cost savings of removing print newspaper requirements. As for the costs associated with online job posting, the Departments agree with the commenter's concern that DOL may have underestimated the cost of online advertising. As explained elsewhere in this preamble, the Departments have concluded that, to reduce this cost and burden, expand the reach of each ad, and leverage DOL's existing technology and infrastructure, it is appropriate for DOL rather than employers to place H–2B electronic advertisements. The final rule replaces the print newspaper-advertising requirement with employers' job opportunities posted on a DOL-maintained website, *SeasonalJobs.dol.gov,* thus eliminating the cost to employers. Additionally, the enhancements DOL has and continues to make to *SeasonalJobs.dol.gov* are designed to further the Departments' goal to promote greater public awareness of and access to H–2B job opportunities in order to increase the likelihood that U.S. workers interested in nonagricultural opportunities, as well as intermediaries providing services to those workers, receive timely notice of H–2B job opportunities. Any costs or burden that an employer incurs reviewing increased applications from U.S. workers is a fundamental obligation for choosing to participate in the H–2B program and outweighed by the Departments' statutory obligation to ensure that able, willing, and qualified U.S. workers are not available. As explained above, DOL has also estimated the cost savings from eliminating the document retention requirement. In terms of cost impacts on job seekers, the costs of searching and applying for a job electronically are less than the cost associated with searching and applying for a job through a newspaper recruitment advertisement.[11]

Four commenters asserted that the analysis did not consider the effect the rule would have on the newspaper industry, though three of these commenters acknowledged that the proposed rule estimated that lost revenue would equal $9.45 million. While this rule may have an effect on the newspaper industry, the advertising revenue lost from employers who are no longer required to post job openings in print is expected to represent an insignificant portion of the industry's overall advertisement revenue.[12]

2. Subject-by-Subject Analysis

The Departments' analysis below considers the expected impacts of the following aspects of the final rule against the baseline (*i.e.,* the 2015 Interim Final Rule (80 FR 24042 (Apr. 29, 2015)): (a) Rescission of the requirement that an employer advertise its job opportunity in a print newspaper of general circulation in the area of intended employment; (b) elimination of the document retention requirement associated with print newspaper advertisements; and (c) the time it takes the regulated community to read and review the rule.

(a) Eliminating the Use of Print Newspaper Advertisements

This final rule modernizes H–2B recruitment by rescinding the regulation at 20 CFR 655.42 imposing the requirement for print newspaper advertisements, and amending the regulation at 20 CFR 655.41(a) to delete reference to the content of print advertisements. In conjunction with this rule, DOL will assume responsibility for these recruitment activities by advertising each employer's job opportunity on a DOL website designed to make the job opportunity more broadly available to U.S. workers.

To estimate the cost savings to employers that would result from this final rule, the Departments multiplied the average number of H–2B labor certifications issued each fiscal year by the average cost to an employer of placing a print advertisement. First, the Departments used program data for FYs 2015–2017 to estimate that DOL approves, on average, 5,879 H–2B labor certifications each fiscal year.[13] To estimate the average cost of a print ad, the Departments identified the top five states where prospective H–2B employers received temporary labor certifications,[14] and researched the cost of placing a newspaper advertisement in the most populous city in each of these states (for several newspapers, including large and local papers), for advertisements satisfying the content requirements set forth in § 655.41. Based

[11] The Departments acknowledge that some job seekers may not have access to the internet. For this group of job seekers, it may not necessarily be less costly to search and apply for a job online. However, the Departments believe that the number of job seekers without internet access is a small portion of the population.

[12] The total estimated advertising revenue for the newspaper industry in 2018 was $14.3 billion (*https://www.journalism.org/fact-sheet/newspapers/*).

[13] The average is based on 5,106 H–2B certifications in FY 2015; 5,933 certifications in FY 2016; and 6,599 certifications in FY 2017. *See https://www.foreignlaborcert.doleta.gov/performancedata.cfm.*

[14] The top five states where employers seek to place H–2B workers are Colorado, Florida, Louisiana, Texas, and Virginia.

on this data, the Departments estimated that, on average, it costs an employer $803.08 to place a single advertisement (one day) complying with § 655.41's content requirements.

Thus, placing the advertisement on two separate days, as required by § 655.42, costs an employer, on average, twice as much, or $1,606 ($803 for each advertisement).

As mentioned above, employers can advertise using the DOL-maintained website free of charge, so removing the requirement to advertise in a print newspaper would result in a cost savings equal to the cost of complying with the current regulation. Although § 655.42 currently requires that one of the advertising days be a Sunday, the Departments did not identify a significant difference in cost between advertisements placed on Sundays and weekdays. Therefore, the Departments did not distinguish between these two costs when calculating total advertising cost savings.

To estimate the annual newspaper advertising costs that employers will avoid under the final rule, the Departments multiplied the estimated annual number of H–2B temporary labor certifications (5,879) by the average newspaper advertising cost of $1,606. This yielded annual cost savings of $9.44 million. The annualized cost savings over the 10-year period is $9.44 at both discount rates of 3 and 7 percent. The Departments believe that the cost to DOL of upgrading its database and posting an employer's job opportunity on its website would be *de minimis* on an annual basis.

(b) Eliminating Document Retention Requirements

The final rule amends § 655.56 to eliminate the document retention requirement at § 655.56(c)(2)(ii) associated with print newspaper advertisements. To estimate the cost savings from this revision, the Departments calculated the average cost for each employer to retain print advertisements records for each H–2B certification. To do so, the Departments multiplied each employer's per-certification staff time by its per-certification staff cost. The Departments estimate that it takes a human resources (HR) specialist, on average, two minutes to store (print and file) proof of print advertisement. The Departments used the median hourly wage rate of an HR specialist at a nonagricultural business ($31.84) [15] then adjusted the base wage rate using a loaded wage factor (1.63) [16] to account for fringe benefits and overhead. The Departments then multiplied the resulting wage rate by the staff time (two minutes), which yielded a cost of $1.73 per certification. As explained above, the Departments estimate that DOL issues, on average, 5,879 H–2B labor certifications each fiscal year. By multiplying the estimated annual number of certifications by the cost per certification ($1.73), the Departments estimated an annual cost savings of $10,171. The annualized cost savings over the 10-year period is $10,171 at both discounts rates of 3 percent and 7 percent.

(c) Time To Review and Understand the Rule

During the first year after this rule takes effect, employers seeking H–2B workers will need time to learn about the new requirements. The Departments assume that many employers participating in the H–2B program will learn about the requirements of the new rule from an industry newsletter or bulletin. The Departments estimate that an employer will require approximately 10 minutes to understand the rule change, as this final rule addresses only the job-advertising and document retention requirements for employers seeking H–2B workers, and eliminates those requirements without replacing them with new ones.

The requirement to review and understand the rule represents a cost to employers participating in the H–2B program only in the first year of the rule. The Departments estimate this cost for each employer by multiplying the staff time required to read and review the new rule by the estimated staff cost. As above, the Departments estimated a wage rate by multiplying the median hourly wage of an HR specialist at a nonagricultural business ($31.84) by the loaded wage rate (1.63) to account for fringe benefits and overhead. The Departments then multiplied the resulting wage rate by the required staff time (10 minutes), which yielded a cost of $8.65 per employer. The Departments estimated the total cost of reading and reviewing the rule by multiplying $8.64 by the average annual number of employers participating in the H–2B program over FY 2015–2017 (5,326).[17] This calculation results in a cost of $46,069 in the first year the rule is in effect. The annualized cost over the 10-year period is $5,243 and $6,130 at the discount rates of 3 percent and 7 percent, respectively.

3. Summary of Impacts

The Departments estimate the total first-year cost of the final rule to be $46,069. This cost results from the time required to read and review the final rule for the average annual number of unique H–2B employer applicants (based on FY 2015–2017 data). The Departments estimate total first-year cost savings of $9.45 million. This cost savings results from eliminating the requirement that employers place print newspaper advertisements and retain ad-related documents. Net first-year cost savings, therefore, amount to $9.41 million.

Generally, annual cost savings are expected to be $9.45 million in every year following the first. The 10-year discounted net cost savings of the rule range from $80.59 million to $66.35 million (with 3 percent and 7 percent discount rates, respectively). The annualized net cost savings of the final rule is $9.45 at both the 3 percent and 7 percent discount rates. When the Departments use a perpetual time horizon to allow for cost comparisons under E.O. 13771, the annualized cost savings of this final rule are $7.57 million at a discount rate of 7 percent.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121 (March 29, 1996), requires federal agencies engaged in rulemaking to consider the impact of their proposals on small entities, consider alternatives to minimize that impact, and solicit public comment on their analyses. The RFA requires the assessment of the direct effects [18] of a regulation on a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions. Agencies must perform a review to determine whether a proposed or final rule would have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603 and 604.

This final rule may impact small businesses that request H–2B temporary labor certification. The Departments

[15] Wage derived from Bureau of Labor Statistics median hourly wage for HR Specialists (occupational code 13–1071), May 2017.

[16] The loaded wage factor is calculated using a fringe benefit rate of 46 percent, which is based on the Bureau of Labor Statistics Employer Cost for Employee Compensation data. This fringe benefit rate was added to an overhead rate of 17 percent, which is based on DOL practices.

[17] The average is based on 4,764 unique H–2B employer applicants in FY 2015; 5,296 employers in FY 2016; and 5,917 employers in FY 2017.

[18] Because this rule does not directly regulate newspapers, the rule's potential effects on newspaper revenue are outside the scope of this specific analysis. The Departments note, however, that these effects are discussed above.

assume that the average number of H–2B certifications requested by any small business per year would be one. The Departments estimate that small businesses would incur a one-time cost of $8.65 to familiarize themselves with the rule and would incur annual cost savings of $1,606 associated with advertising online rather than in print newspapers. In addition, the Departments estimate that a small business would incur annual cost savings of $1.63 related to the elimination of the document retention requirement. Over a 10-year analysis period, the net annualized cost savings for a small business would be $1,719 at a 7-percent discount rate.

The Departments reviewed the impacts of the proposed rule for two North American Industry Classification System (NAICS) Codes that frequently request H–2B certification: NAICS 561730: Landscaping Services, and NAICS 721110: Hotels (except Casino Hotels) and Motels. The Small Business Administration estimates that revenue for a small business with NAICS Code 561730 is $7.5 million and for NAICS Code 721110 is $32.5 million.[19] The impact of the final rule would be less than 1 percent of annual revenue for the smallest businesses in these industries with an employment size fewer than five ($197,491 for NAICS 561730 and $321,239 for NAICS 721110).[20] Based on this determination, the Departments certify that this final rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* provides that a Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. DOL has submitted the Information Collection Request (ICR) contained in this final rule to OMB and obtained approval using emergency clearance procedures outlined at 5 CFR 1320.13.

This final rule modernizes and improves the labor market test that DOL uses to assess whether qualified U.S. workers are available by: (1) Rescinding the requirement that an employer advertise its job opportunity in a print newspaper of general circulation in the area of intended employment; and (2) expanding and enhancing the Department's electronic job registry. More specifically, this final rule eliminates the general requirement for a prospective H–2B employer to advertise its job opportunity in a print newspaper of general circulation in the area of intended employment. However, in contrast to the NPRM, this final rule does not require the employer to place an electronic advertisement on a website that is widely viewed and appropriate for use by workers who are likely to apply for the job opportunity in the area of intended employment. Rather, as explained in detail in this final rule, DOL will advertise the employer's job opportunity on the employer's behalf on *SeasonalJobs.dol.gov,* an expanded and improved version of DOL's existing H–2B job registry website.

During the NPRM stage of this rule, DOL requested the creation of a new OMB Control Number 1205–0534 to account for the time burden and cost associated with the online recruitment process. However, upon further consideration and in light of the revised requirements in the final rule, it is appropriate, instead, to revise the existing OMB Control Number 1205–0509 to account for the burden and costs associated with requiring online ads only, and for the transfer of this burden from employers to DOL. DOL is seeking OMB's approval under PRA emergency procedures to revise 1205–0509 to accommodate this change.

The information collection requirements associated with OMB Control Number 1205–0509, are revised under this final rule as follows. This burden breakdown only reflects the updated burden with regard to the advertisement requirement:

Agency: DOL–ETA.

Type of Information Collection: Currently approved.

Title of the Collection: Advertising Requirements for Employers Seeking to Employ H–2B Nonimmigrant Workers.

Agency Form Number: ETA 9142B, instructions and accompanying appendixes.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 5,879.

Average Responses per Year per Respondent: 2.

Total Estimated Number of Responses: 11,758.

Average Time per Response: 7 minutes per application.

Total Estimated Annual Time Burden: 0 hours. (Employers will not be burdened with the advertisement requirements.)

Total Estimated Other Costs Burden: $0

D. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector.

This final rule does not exceed the $100 million expenditure in any 1 year when adjusted for inflation, and this rulemaking does not contain such a mandate. The requirements of Title II of the Act, therefore, do not apply, and the Departments have not prepared a statement under the Act.

E. Small Business Regulatory Enforcement Fairness Act of 1996

This final rule would not be a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996, Public Law 104–121, 804, 110 Stat. 847, 872 (1996), 5 U.S.C. 804(2). The Office of Information and Regulatory Affairs has found that this final rule is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic or export markets.

F. Executive Order 13132: Federalism

This final rule does not have federalism implications because it would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

[19] U.S. Small Business Administration (2017), *Table of Small Business Size Standards Matched to North American Industry Classification System Codes,* retried from: *https://www.naics.com/wp-content/uploads/2017/10/SBA_Size_Standards_Table.pdf.*

[20] U.S. Census, *2012 SUSB Annual Data Tables by Establishment Industry, https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html.*

Accordingly, Executive Order 13132, Federalism, requires no further agency action or analysis.

G. Executive Order 13175, Indian Tribal Governments

This final rule does not have ''tribal implications'' because it would not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Accordingly, Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, requires no further agency action or analysis.

H. The Treasury and General Government Appropriations Act of 1999: Assessment of Federal Regulations and Policies on Families

This final rule would have no effect on family well-being or stability, marital commitment, parental rights or authority, or income or poverty of families and children. Accordingly, section 654 of the Treasury and General Government Appropriations Act of 1999 (5 U.S.C. 601 note) requires no further agency action, analysis, or assessment.

I. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This final rule would have no adverse impact on children. Accordingly, Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, as amended by Executive Orders 13229 and 13296, requires no further agency action or analysis.

J. Environmental Impact Assessment

This final rule is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This final rule is therefore categorically excluded from further review under the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321–4375.

K. Executive Order 13211, Energy Supply

This final rule has not been identified to have impacts on energy supply. Accordingly, Executive Order 13211 requires no further agency action or analysis.

L. Executive Order 12630, Constitutionally Protected Property Rights

This final rule will not implement a policy with takings implications. Accordingly, Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, requires no further agency action or analysis.

M. Executive Order 12988, Civil Justice Reform Analysis

This final rule was drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform. It was written to provide a clear legal standard for affected conduct and was carefully reviewed to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the Federal court system. It meets the applicable standards provided in section 3 of Executive Order 12988.

List of Subjects

20 CFR Part 655

Administrative practice and procedure, Employment, Employment and training, Enforcement, Foreign workers, Forest and forest products, Fraud, Health professions, Immigration, Labor, Longshore and harbor work, Migrant workers, Nonimmigrant workers, Passports and visas, Penalties, Reporting and recordkeeping requirements, Unemployment, Wages, Working conditions.

29 CFR Part 503

Administrative practice and procedure, Employment, Foreign Workers, Housing, Housing standards, Immigration, Labor, Nonimmigrant workers, Penalties, Transportation, Wages.

Accordingly, part 655 of title 20 and part 503 of title 29 of the Code of Federal Regulations are amended as follows:

Title 20—Employees' Benefits

PART 655—TEMPORARY EMPLOYMENT OF FOREIGN WORKERS IN THE UNITED STATES

■ 1. The authority citation for part 655 continues to read as follows:

Authority: Section 655.0 issued under 8 U.S.C. 1101(a)(15)(E)(iii), 1101(a)(15)(H)(i) and (ii), 8 U.S.C. 1103(a)(6), 1182(m), (n), and (t), 1184(c), (g), and (j), 1188, and 1288(c) and (d); sec. 3(c)(1), Pub. L. 101–238, 103 Stat. 2099, 2102 (8 U.S.C. 1182 note); sec. 221(a), Pub. L. 101–649, 104 Stat. 4978, 5027 (8 U.S.C. 1184 note); sec. 303(a)(8), Pub. L. 102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 323(c), Pub. L. 103–206, 107 Stat. 2428; sec. 412(e), Pub. L. 105–277, 112 Stat. 2681 (8 U.S.C. 1182 note); sec. 2(d), Pub. L. 106–95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); 29 U.S.C. 49k; Pub. L. 107–296, 116 Stat. 2135, as amended; Pub. L. 109–423, 120 Stat. 2900; 8 CFR 214.2(h)(4)(i); 8 CFR 214.2(h)(6)(iii); and sec. 6, Pub. L. 115–218, 132 Stat. 1547 (48 U.S.C. 1806).

Subpart A issued under 8 CFR 214.2(h).

Subpart B issued under 8 U.S.C. 1101(a)(15)(H)(ii)(a), 1184(c), and 1188; and 8 CFR 214.2(h).

Subpart E issued under 48 U.S.C. 1806.

Subparts F and G issued under 8 U.S.C. 1288(c) and (d); sec. 323(c), Pub. L. 103–206, 107 Stat. 2428; and 28 U.S.C. 2461 note, Pub. L. 114–74 at section 701.

Subparts H and I issued under 8 U.S.C. 1101(a)(15)(H)(i)(b) and (b)(1), 1182(n) and (t), and 1184(g) and (j); sec. 303(a)(8), Pub. L. 102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 412(e), Pub. L. 105–277, 112 Stat. 2681; 8 CFR 214.2(h); and 28 U.S.C. 2461 note, Pub. L. 114–74 at section 701.

Subparts L and M issued under 8 U.S.C. 1101(a)(15)(H)(i)(c) and 1182(m); sec. 2(d), Pub. L. 106–95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); Pub. L. 109–423, 120 Stat. 2900; and 8 CFR 214.2(h).

■ 2. Amend § 655.19 by revising paragraph (e)(1) to read as follows:

§ 655.19 Job contractor filing requirements.

* * * * *

(e)(1) Either the job contractor or its employer-client may place the required job order and conduct recruitment as described in §§ 655.16 and 655.43 through 655.46. Also, either one of the joint employers may assume responsibility for interviewing applicants. However, both of the joint employers must sign the recruitment report that is submitted to the NPC with the *Application for Temporary Employment Certification,* ETA Form 9142B.

* * * * *

■ 3. Amend § 655.40 by revising paragraph (b) to read as follows:

§ 655.40 Employer-conducted recruitment.

* * * * *

(b) *Employer-conducted recruitment period.* Unless otherwise instructed by the CO, the employer must conduct the recruitment described in §§ 655.43 through 655.46 within 14 calendar days from the date the Notice of Acceptance is issued. All employer-conducted recruitment must be completed before the employer submits the recruitment report as required in § 655.48.

* * * * *

■ 4. Amend § 655.41 by revising paragraph (a) to read as follows:

§ 655.41 Advertising requirements.

(a) All recruitment conducted under §§ 655.43 through 655.46 must contain terms and conditions of employment that are not less favorable than those offered to the H–2B workers and, at a minimum, must comply with the assurances applicable to job orders as set forth in § 655.18(a).

* * * * *

§ 655.42 [Removed and Reserved]

■ 5. Remove and reserve § 655.42.

§ 655.56 [Amended]

■ 6. Amend § 655.56 by removing paragraph (c)(2)(ii) and redesignating paragraphs (c)(2)(iii), (iv), and (v) as paragraphs (c)(2)(ii), (iii), and (iv), respectively.

■ 7. Amend § 655.71 by revising paragraph (c)(2) to read as follows:

§ 655.71 CO-ordered assisted recruitment.

* * * * *

(c) * * *

(2) Designating the sources where the employer must recruit for U.S. workers and directing the employer to place the advertisement(s) in such sources;

* * * * *

Title 29—Labor

PART 503—ENFORCEMENT OF OBLIGATIONS FOR TEMPORARY NONIMMIGRANT NON–AGRICULTURAL WORKERS DESCRIBED IN THE IMMIGRATION AND NATIONALITY ACT

■ 8. The authority citation for part 503 continues to read as follows:

Authority: 8 U.S.C. 1101(a)(15)(H)(ii)(b); 8 U.S.C. 1184; 8 CFR 214.2(h); 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990); Pub. L. 114–74 at § 701.2.

§ 503.17 [Amended]

■ 9. Amend § 503.17 by removing paragraph (c)(2)(ii) and redesignating paragraphs (c)(2)(iii), (iv), and (v) as paragraphs (c)(2)(ii), (iii), and (iv), respectively.

Kevin K. McAleenan,

Acting Secretary of Homeland Security.

Eugene Scalia,

Secretary of Labor.

[FR Doc. 2019–24832 Filed 11–13–19; 4:15 pm]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 126

RIN 3245–AH06

HUBZone Program Provisions for Governor-Designated Covered Areas

AGENCY: U.S. Small Business Administration.

ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule contains amendments to the regulations governing the HUBZone Program. The U.S. Small Business Administration (SBA) is making changes to its regulations to implement provisions of the National Defense Authorization Act for Fiscal Year 2018 which authorized the inclusion of ''Governor-designated covered areas'' under the HUBZone program. This direct final rule would merely replicate these statutory changes into SBA's regulations.

DATES: This rule is effective on January 1, 2020, without further action, unless significant adverse comment is received by December 16, 2019. If significant adverse comment is received, SBA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments, identified by RIN 3245–AH06, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *For Mail, Paper, Disk, or CD–ROM Submissions:* Bruce Purdy, U.S. Small Business Administration, Office of the HUBZone Program, 409 Third Street SW, 8th Floor, Washington, DC 20416.
- *Hand Delivery/Courier:* Bruce Purdy, U.S. Small Business Administration, Office of the HUBZone Program, 409 Third Street SW, 8th Floor, Washington, DC 20416.

SBA will post all comments on *www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* please submit the information to Bruce Purdy, U.S. Small Business Administration, Office of the HUBZone Program, 409 Third Street SW, 8th Floor, Washington, DC 20416, or send an email to *hubzone@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination on whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Bruce Purdy, Deputy Director, Office of the HUBZone Program, 409 Third Street SW, Washington, DC 20416, 202–205–7554, *hubzone@sba.gov.*

SUPPLEMENTARY INFORMATION: This direct final rule implements a conforming amendment to SBA's regulations from the National Defense Authorization Act for Fiscal Year 2018, Public Law 115–91 (2018 NDAA). The 2018 NDAA became effective on December 12, 2017. Section 1701(e) of the 2018 NDAA authorized the inclusion of ''Governor-designated covered areas'' under the HUBZone program. Section 1701(j) of the 2018 NDAA provides that section 1701(e) shall be effective January 1, 2020.

SBA seeks to amend its HUBZone rules to mirror the changes made to the Small Business Act, to avoid public confusion and possible misinterpretations of SBA's HUBZone program. Since these are conforming amendments, with no extraneous interpretation or other expanded materials, SBA expects no significant adverse comments. Therefore, SBA has decided to proceed with a direct final rule. If SBA receives a significant adverse comment during the comment period, SBA will withdraw the rule, and proceed with a new proposed rule.

In order to implement the changes made by section 1701(e) of the 2018 NDAA, SBA is amending § 126.103 of its regulations by adding a new definition for the term ''Governor-designated covered area'', revising the definition of the term ''HUBZone'' to include Governor-designated covered areas, and adding a new § 126.104 to implement the statutory process by which a Governor can petition and the SBA Administrator may designate a specific covered area to be a qualified HUBZone area. The statute provides the guidelines under which a petition will be considered. Specifically, the Administrator will consider the following: The potential for job creation and investment in the covered area; the demonstrated interest of small business concerns in the covered area to be designated as a Governor-designated covered area; how State and local government officials have incorporated the covered area into an economic development strategy; and if the covered area was a HUBZone before becoming the subject of the petition, the impact on the covered area if the Administrator did not approve the petition. SBA anticipates that included within the covered areas that a Governor may seek to be designated as a qualified HUBZone area are Opportunity Zones, authorized by Section 13823 of the Tax Cuts and Jobs Act of 2017, Public Law 115–97, that do not otherwise qualify as HUBZones.

Compliance With Executive Orders 12866, 13771, 13563, 12988, 13132, 13175, the Paperwork Reduction Act (44 U.S.C. Ch. 35), the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Administrative Procedure Act

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this direct final rule does not constitute a significant regulatory action under Executive Order 12866. This rule is also

not a major rule under Congressional Review Act.

Executive Order 13771

This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Executive Order 13563

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 also requires that regulations be based on the open exchange of information and perspectives among state and local officials, affected stakeholders in the private sector, and the public as a whole. SBA has developed this rule in a manner consistent with these requirements. While developing this rule, SBA responded to specific inquiries from government officials and the public regarding the implementation of the statutory authority for Governor-designated covered areas and discussed the implementation of the authority at nationwide conferences, including the HUBZone Council Conference. SBA continues to communicate with the public by responding to inquiries regarding this new authority.

Executive Order 12988

This action meets applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This direct final rule would allow State Governors to petition SBA to designate as HUBZones certain areas that would otherwise not qualify as HUBZones. A Governor's petition must delineate the areas to be included and show: (1) The potential for job creation and investment in the covered area; (2) the demonstrated interest of small business concerns in the covered area to be designated as a Governor-designated covered area; (3) how State and local government officials have incorporated the covered area into an economic development strategy; and (4) if the covered area was a HUBZone before becoming the subject of the petition, the impact on the covered area if the Administrator did not approve the petition. Governors may only submit one petition for their State every year and must annually provide data on Governor-designated covered areas previously approved by the SBA Administrator.

We have analyzed this direct final rule and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Executive Order 13175

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Paperwork Reduction Act, 44 U.S.C. Ch. 35

SBA has determined that this direct final rule imposes reporting requirements under the Paperwork Reduction Act (PRA). Specifically, the rule would require State Governors to submit petitions to SBA in order for SBA to determine whether to designate certain areas as Governor-designated covered areas. At a minimum, such petitions would provide a list of covered areas for which the Governor requests designation and information on the potential for job creation and investment in the covered area, the demonstrated interest of small business concerns in the covered area to be designated as a Governor-designated covered area, how State and local government officials have incorporated the covered area into an economic development strategy, and if the covered area was a HUBZone before becoming the subject of the petition, the impact on the covered area if the Administrator did-not approve the petition. As permitted by 13 CFR 1320.13, SBA sought emergency PRA review and approval of this information collection, including waiver of the required 60-day public comment notice, from the Office of Management and Budget (OMB). OMB approved SBA's request and assigned OMB Control Number 3245–0403. Before this approval expires on April 30, 2020, SBA will publish the 60-day notice in the **Federal Register** and resubmit this information collection to OMB for standard review. The disposition of any comments received will be addressed with that resubmission.

Regulatory Flexibility Act, 5 U.S.C. 601–612

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, small non-profit enterprises, and small local governments. Pursuant to the RFA, when an agency issues a rulemaking, the agency must prepare a regulatory flexibility analysis which describes the impact of the rule on small entities. However, section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. Within the meaning of the RFA, SBA certifies that this direct rule will not have a significant economic impact on a substantial number of small entities.

Administrative Procedure Act—Justification for Direct Final Rule

In general, SBA publishes a rule for public comment before issuing a final rule, in accordance with the Administrative Procedure Act, 5 U.S.C. 553. The Administrative Procedure Act provides an exception to this standard rulemaking process, however, where an agency finds good cause to adopt a rule without prior public participation. 5 U.S.C. 553(b)(3)(B). The good cause requirement is satisfied when prior public participation is impracticable, unnecessary, or contrary to the public interest.

SBA is publishing this rule as a direct final rule because public participation is unnecessary. SBA views this as a non-controversial administrative action because it merely implements a change required by the Small Business Act, as amended by section 1701(e) of the National Defense Authorization Act for Fiscal Year 2018, Public Law 115–91 (2018 NDAA). This rule will be effective on the date shown in the **DATES** section unless SBA receives any significant adverse comments on or before the deadline for comments set forth in the **DATES** section. Significant adverse comments are comments that provide

strong justifications why the rule should not be adopted or for changing the rule. SBA does not expect to receive any significant adverse comments because the rule simply mirrors the statutory language contained in section 1701(e) of the 2018 NDAA, with no extraneous interpretation or other expanded text. Implementation of this change will benefit the public by expanding the HUBZone program and will allow SBA to meet the statutory deadline mandated by section 1701(j) of the 2018 NDAA, which provides that this change is effective January 1, 2020. If SBA receives any significant adverse comments, SBA will publish a notice in the **Federal Register** withdrawing this rule before the effective date. If SBA receives no significant adverse comments, SBA will publish a document in the **Federal Register** confirming the effective date.

List of Subjects in 13 CFR Part 126

Administrative practice and procedure, Government procurement, Small businesses.

Accordingly, for the reasons stated in the preamble, SBA amends 13 CFR part 126 as follows:

PART 126—HUBZONE PROGRAM

■ 1. The authority for 13 CFR part 126 continues to read as follows:

Authority: 15 U.S.C. 632(a), 632(j), 632(p), 644 and 657a.

■ 2. Amend § 126.103 by adding a definition alphabetically for the term ''Governor-designated covered area'' and revising the definition of the term ''HUBZone'' to read as follows:

§ 126.103 What definitions are important in the HUBZone program?

* * * * *

Governor-designated covered area means an area that the Administrator has designated as a HUBZone by approving a Governor-generated petition as described in § 126.104.

HUBZone means a historically underutilized business zone, which is an area located within one or more:

(1) Qualified census tracts;

(2) Qualified non-metropolitan counties;

(3) Lands within the external boundaries of an Indian reservation;

(4) Redesignated areas;

(5) Qualified base closure areas;

(6) Qualified disaster areas; or

(7) Governor-designated covered areas.

* * * * *

■ 3. Add § 126.104 to read as follows:

§ 126.104 How can a Governor petition for the designation of a Governor-designated covered area?

(a) For a specific covered area to receive a designation as a Governor-designated covered area, the Governor of the State in which the identified covered area is wholly contained shall include such area in a petition to the Administrator requesting such a designation. In reviewing a request for designation included in such a petition, the Administrator may consider—

(1) The potential for job creation and investment in the covered area;

(2) The demonstrated interest of small business concerns in the covered area to be designated as a Governor-designated covered area;

(3) How State and local government officials have incorporated the covered area into an economic development strategy; and

(4) If the covered area was a HUBZone before becoming the subject of the petition, the impact on the covered area if the Administrator did not approve the petition.

(b) Each calendar year, a Governor may submit not more than 1 petition described in this section. Such petition shall include all covered areas in a State for which the Governor seeks designation as a Governor-designated covered area, except that the total number of covered areas included in such petition may not exceed 10 percent of the total number of covered areas in the State.

(c) If the Administrator grants a petition described in this section, the Governor of the Governor-designated covered area shall, not less frequently than annually, submit data to the Administrator certifying that each Governor-designated covered area continues to meet the requirements of paragraph (d)(1) of this section.

(d) In this section:

(1) The term ''covered area'' means an area in a State—

(i) That is located outside of an urbanized area, as determined by the Bureau of the Census;

(ii) With a population of not more than 50,000; and

(iii) For which the average unemployment rate is not less than 120 percent of the average unemployment rate of the United States or of the State in which the covered area is located, whichever is less, based on the most recent data available from the American Community Survey conducted by the Bureau of the Census.

(2) The term ''Governor'' means the chief executive of a State.

(3) The term ''State'' means each of the States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, or American Samoa.

Christopher Pilkerton,

Acting Administrator.

[FR Doc. 2019–24610 Filed 11–14–19; 8:45 am]

BILLING CODE P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe certain interest assumptions under the regulation for plans with valuation dates in December 2019. These interest assumptions are used for paying certain benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective December 1, 2019.

FOR FURTHER INFORMATION CONTACT: Gregory Katz (*katz.gregory@pbgc.gov*), Attorney, Regulatory Affairs Division, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, 202–326–4400 ext. 3829. (TTY users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4400, ext. 3829.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminated single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974 (ERISA). The interest assumptions in the regulation are also published on PBGC's website (*https://www.pbgc.gov*).

PBGC uses the interest assumptions in appendix B to part 4022 (''Lump Sum Interest Rates for PBGC Payments'') to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Because some private-sector pension plans use these interest rates to determine lump sum amounts payable to plan participants (if the

resulting lump sum is larger than the amount required under section 417(e)(3) of the Internal Revenue Code and section 205(g)(3) of ERISA), these rates are also provided in appendix C to part 4022 (''Lump Sum Interest Rates for Private-Sector Payments'').

This final rule updates appendices B and C of the benefit payments regulation to provide the rates for December 2019 measurement dates.

The December 2019 lump sum interest assumptions will be 0.25 percent for the period during which a benefit is (or is assumed to be) in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for November 2019, these assumptions represent no change in the immediate rate and are otherwise unchanged.

PBGC updates appendices B and C each month. PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to issue new interest assumptions promptly so that they are available for plans that rely on our publication of them each month to calculate lump sum benefit amounts.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during December 2019, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, rate set 314 is added at the end of the table to read as follows:

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
314	12–1–19	1–1–20	0.25	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, rate set 314 is added at the end of the table to read as follows:

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
314	12–1–19	1–1–20	0.25	4.00	4.00	4.00	7	8

Issued in Washington, DC, by

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2019–24729 Filed 11–14–19; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF THE TREASURY

31 CFR Part 50

RIN 1505–AC62

IMARA Calculation Under the Terrorism Risk Insurance Program

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury (Treasury) is issuing this final rule to implement technical changes to program regulations that address the calculation and notification to the public of the Terrorism Risk Insurance Program's (Program) insurance marketplace aggregate retention amount (IMARA) under the Terrorism Risk Insurance Act (Act), as amended. The changes were published in proposed form for public comment on September 6, 2019.

DATES: This rule is effective December 16, 2019.

FOR FURTHER INFORMATION CONTACT: Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, 202–622–2922 or Lindsey Baldwin, Senior Policy Analyst, Federal Insurance Office, 202–622–3220.

SUPPLEMENTARY INFORMATION:

I. Background

The Terrorism Risk Insurance Act of 2002 (as amended, the Act or TRIA) [1] was enacted on November 26, 2002, following the attacks of September 11, 2001, to address disruptions in the

[1] Public Law 107–297, 116 Stat. 2322, codified at 15 U.S.C. 6701 note. Because the provisions of TRIA (as amended) appear in a note instead of particular sections of the U.S. Code, the provisions of TRIA are identified by the sections of the law.

market for terrorism risk insurance, to help ensure the continued availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for the private markets to stabilize and build insurance capacity to absorb any future losses for terrorism events.[2] TRIA requires insurers to ''make available'' terrorism risk insurance for commercial property and casualty losses resulting from certified acts of terrorism (insured losses), and provides for shared public and private compensation for such insured losses. The Program has been reauthorized three times, most recently by the Terrorism Risk Insurance Program Reauthorization Act of 2015 (2015 Reauthorization Act).[3]

The Secretary of the Treasury (Secretary) administers the Program. The Federal Insurance Office (FIO) assists the Secretary in administering the Program.[4] To assist insurers, policyholders, and other interested parties in complying with the applicable requirements of the Act, Treasury has issued regulations implementing the Program. In some instances, Treasury has also issued interim guidance to be relied upon by insurers until superseded by any regulations.[5] Most recently, Treasury issued regulations implementing the changes to the Program required under the 2015 Reauthorization Act.[6]

The Act established an industry marketplace aggregate retention amount (IMARA) as a threshold figure to determine whether any Treasury payments under the Program are subject to mandatory recoupment. Under the Act, if total annual payments by participating insurers are below the IMARA, Treasury must recoup all amounts expended by it up to the IMARA threshold (mandatory recoupment). If total annual payments by participating insurers are above the IMARA, Treasury has the discretion to recoup all expended amounts above the IMARA threshold (discretionary recoupment).[7]

The 2015 Reauthorization Act provided for a schedule of defined IMARA values from calendar year 2015 through calendar year 2019. The 2015 Reauthorization Act also provided that for calendar year 2020 and future years the IMARA ''shall be revised to be the amount equal to the annual average of the sum of insurer deductibles for all insurers participating in the Program for the prior 3 calendar years,'' as such sum is determined pursuant to a rule issued by the Secretary.[8] The rule change adopted in this notice solely addresses the manner in which Treasury calculates the IMARA and the timing of public notification of the IMARA calculation.

II. The Proposed Rule

The proposed rule on which this final rule is based was published in the **Federal Register** at 84 FR 46907 on September 6, 2019. The proposed rule would make a technical correction to 31 CFR 50.4(m)(2)(i), originally implemented in 2016, to clarify that the IMARA calculation is based upon direct earned premium reported to Treasury by insurers in Treasury's annual data call ''*in*'' the three calendar years prior to the calendar year in question, instead of ''*for*'' the three calendar years prior to the calendar year in question. For example, this would result in a proper calculation of the 2020 IMARA by referring to the insurer deductibles for the previous three years (2019, 2018, and 2017), which are based on reported data for calendar years 2018, 2017, and 2016.[9] In addition, the proposed rule accelerates the notification date of the IMARA calculation by Treasury, from no later than April 30 of the year in question to no later than December 31 of the prior calendar year. That acceleration will improve administrative efficiency and provide greater certainty to insurers and policyholders.

III. Summary of Comments and Final Rule

Treasury received one comment regarding the proposed changes concerning the IMARA calculation and the date of notification of the IMARA calculation to the public. This comment was in favor of both of the proposed changes.[10] Accordingly, Treasury is issuing this final rule based upon the proposed rule without change.

IV. Procedural Requirements

Executive Order 12866, ''*Regulatory Planning and Review.*'' This rule is not a significant regulatory action for purposes of Executive Order 12866, ''Regulatory Planning and Review,'' and thus has not been reviewed by the Office of Management and Budget (OMB).

Regulatory Flexibility Act. Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* Treasury must consider whether this rule will have a ''significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). In this case, Treasury certifies that this rule will not have a significant economic impact on a substantial number of small entities. The rule provides for a technical change in the manner in which Treasury will calculate a figure relevant to operation of the Program and to better conform it to Congressional requirements. The only other rule change is to provide for earlier notice to insurers of the IMARA calculation than the existing rule. It has no effect on the collection of the data (including data collected from small entities) under the Program rules.

Paperwork Reduction Act. The rule does not involve the collection of information and thus has not been submitted to OMB for review under the requirements of the Paperwork Reduction Act, 44 U.S.C. 3507(d). The

[2] TRIA, sec. 101(b).

[3] See Terrorism Risk Insurance Extension Act of 2005, Public Law 109–144, 119 Stat. 2660; Terrorism Risk Insurance Program Reauthorization Act of 2007, Public Law 110–160, 121 Stat. 1839; Terrorism Risk Insurance Program Reauthorization Act of 2015, Public Law 114–1, 129 Stat. 3.

[4] 31 U.S.C. 313(c)(1)(D).

[5] Treasury summarized the history of prior rulemakings in connection with the Program in a 2016 proposed rulemaking proposing rule changes to implement the 2015 Reauthorization Act. See 81 FR 18950 (April 1, 2016) (2016 NPRM).

[6] See 81 FR 88592 (December 7, 2016) (Certification Interim Final Rule); 81 FR 93756 (December 21, 2016) (Program Final Rules Except Certification).

[7] See TRIA, sec. 103(e)(7); see also 31 CFR part 50 subpart J (Recoupment and Surcharge Procedures).

[8] TRIA, sec. 103(e)(6)(B)(ii) and (e)(6)(C). An insurer's deductible under the Program for any particular year is 20 percent of its direct earned premium subject to the Program during the preceding year. TRIA, sec. 102(7). For example, an insurer's calendar year 2019 Program deductible is 20 percent of its calendar year 2018 direct earned premium.

[9] The Program rule amended by this final rule was originally proposed in the 2016 NPRM and finalized in the Program Final Rules Except Certification. As explained in the September 2019 notice of proposed rulemaking, although the preamble to the 2016 NPRM correctly explained the methodology for calculating the IMARA in 2020 and beyond, as required by the 2015 Reauthorization Act, the language in the Program rule implemented by the Program Final Rules Except Certification is ambiguous as to how the IMARA should be calculated. Under § 50.4(m)(2)(i) of the Program rules as implemented in 2016, the IMARA calculation is to be based on the ''direct earned premium reported by insurers to Treasury . . . *for* the three calendar years prior to the calendar year in question'' (emphasis added.) This language could be interpreted to mean, for example, that the 2020 IMARA would be calculated using direct earned premiums in 2019, 2018, and 2017, rather than using the data reported in 2019, 2018, and 2017 for calendar years 2018, 2017, and 2016, as intended. This unintended interpretation would be inconsistent with the methodology specified in the 2015 Reauthorization Act and would result in an incorrect IMARA. See generally 84 FR 46907, 46907–08 (Sept. 6, 2019).

[10] See Comment from Underwriters at Lloyd's, London (Oct. 2, 2019), *available at https://www.regulations.gov/docket?D=TREAS-TRIP-2019-0014.*

rule only involves the calculation and public notification of the IMARA in connection with the Program based on data collected by Treasury under rules which have already been subject to OMB review and approval under Control No. 1505–0257.

List of Subjects in 31 CFR Part 50

Insurance, Terrorism.

Authority and Issuance

For the reasons stated in the preamble, 31 CFR part 50 is amended as follows:

PART 50—TERRORISM RISK INSURANCE PROGRAM

■ 1. The authority citation for part 50 continues to read as follows:

Authority: 5 U.S.C. 301; 31 U.S.C. 321; Title I, Pub. L. 107–297, 116 Stat. 2322, as amended by Pub. L. 109–144, 119 Stat. 2660, Pub. L. 110–160, 121 Stat. 1839 and Pub. L. 114–1, 129 Stat. 3 (15 U.S.C. 6701 note) Pub. L. 114–74, 129 Stat. 601, Title VII (28 U.S.C. 2461 note).

■ 2. Amend § 50.4 by revising paragraphs (m)(2) introductory text, (m)(2)(i), and (m)(3) to read as follows:

§ 50.4 Definitions.

* * * * *

(m) * * *

(2) For calendar years beginning with 2020 and any calendar year thereafter as may be necessary, such amount is the lesser of the aggregate amount, for all insurers, of insured losses once there has been a Program Trigger Event during the calendar year and the annual average of the sum of insurer deductibles for all insurers for the prior 3 years, to be calculated by taking:

(i) The total amount of direct earned premium reported by insurers to Treasury pursuant to § 50.51 in the three calendar years prior to the calendar year in question, and then dividing that figure by three; and

* * * * *

(3) For calendar year 2020 and each subsequent calendar year, Treasury shall publish in the **Federal Register** the insurance marketplace aggregate retention amount no later than December 31 of the prior calendar year.

* * * * *

Dated: November 7, 2019.

Bimal Patel,

Assistant Secretary for Financial Institutions.

[FR Doc. 2019–24801 Filed 11–14–19; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0852]

RIN 1625–AA00

Safety Zone; Green River, Rumsey, KY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone for all navigable waters of the Green River from mile marker (MM) 64.0 to MM 65.0. This action is necessary to provide for the safety of life on these navigable waters near Rumsey, KY, during the wire-crossing event. Entry into, transiting through, or anchoring within this zone is prohibited unless authorized by the Captain of the Port Sector Ohio Valley (COTP) or a designated representative.

DATES: This rule is effective from 8 a.m. on November 18, 2019, through 4 p.m. November 22, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0852 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST3 Riley Jackson, Waterways Department Sector Ohio Valley, U.S. Coast Guard; telephone 502–779–5347, email *SECOHV-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Ohio Valley
DHS Department of Homeland Security
FR Federal Register
MM Mile Marker
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this safety zone by November 18, 2019 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is necessary to prevent possible loss of life and property.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with wire-crossing event will present a safety concern on all navigable waters of the Green River extending from mile marker (MM) 64.0 to MM 65.0. The purpose of this rule is to ensure the safety of life and vessels on these navigable waters before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a temporary safety zone that will be enforced from 8 a.m. through 4 p.m. each day, from November 18 through November 22, 2019. The temporary safety zone will cover all navigable waters of the Green River from MM 64.0 to MM 65.0. The duration of the safety zone is intended to ensure the safety of waterway users on these navigable waters before, during, and after the scheduled event. No vessel or person is permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. All persons or vessels desiring entry into or passage through the area must request permission from the COTP or a designated representative. U. S. Coast Guard Sector Ohio Valley may be contacted on VHF Channel 13 or 16, or at 1–800–253–7465.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. This rule impacts one mile of the Green River over five days. Entry into the regulated area will be prohibited from 8 a.m. through 4 p.m. each day, November 18 through November 22, 2019, from Green River MM 64.0 to MM 65.0, unless authorized by the COTP or a designated representative. Moreover, the Coast Guard will issue written Local Notice to Mariners and Broadcast Notice to Mariners via VHF–FM marine channel 16 about the temporary safety zone that is in place.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. While some owners or operators of vessels intending to transit this temporary safety zone, may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 8 hours per day for five days, on all navigable waters extending one mile on part of the Green River. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0852 to read as follows:

§ 165.T08–0852 Safety Zone; Green River, Rumsey KY.

(a) *Location.* The following area is a safety zone: All navigable waters of the Green River from Mile Marker (MM)

64.0 to MM 65.0, extending the entire width of the river.

(b) *Effective period.* This section is in effect from 8 a.m. on November 18, 2019, through 4 p.m. on November 22, 2019.

(c) *Enforcement period.* This section will be enforced from 8 a.m. through 4 p.m. each day from November 18, 2019 through November 22, 2019.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry of vessels or persons into this zone is prohibited unless specifically authorized by the COTP or designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Ohio Valley.

(2) All persons or vessels desiring entry into or passage through the safety zone must request permission from the COTP or a designated representative. U.S. Coast Guard Sector Ohio Valley may be contacted on VHF Channel 13 or 16, or at 1–800–253–7465.

(3) Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(e) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners of any changes in the planned schedule.

Dated: November 12, 2019.

A.M. Beach,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2019–24845 Filed 11–14–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0868]

Safety Zone, Brandon Road Lock and Dam to Lake Michigan Including Des Plaines River, Chicago Sanitary and Ship Canal, Chicago River, and Calumet-Saganashkee Channel, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a segment of the Safety Zone; Brandon Road Lock and Dam to Lake Michigan including Des Plaines River, Chicago Sanitary and Ship Canal, Chicago River, Calumet-Saganashkee Channel on all waters of the Chicago Sanitary and Ship Canal and South Branch of the Chicago River between mile marker 296 and mile marker 296.7 during specified times from November 18, 2019 through November 22, 2019. This action is necessary and intended to protect the safety of life and property on navigable waters prior to, during, and immediately after planned US Army Corps of Engineers work at the Electric Barrier. During the enforcement period listed below, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan or a designated representative.

DATES: The regulations in 33 CFR 165.930 will be enforced from 7 a.m. through 1 p.m. and 3 p.m. through 5 p.m. from November 18, 2019, to November 22, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email LT Tiziana Garner, Waterways Management Division, Marine Safety Unit Chicago, at 630–986–2155, email address *D09-DG-MSUChicago-Waterways@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a segment of the Safety Zone; Brandon Road Lock and Dam to Lake Michigan including Des Plaines River, Chicago Sanitary and Ship Canal, Chicago River, Calumet-Saganashkee Channel, Chicago, IL, listed in 33 CFR 165.930. Specifically, the Coast Guard will enforce this safety zone on all waters of the Chicago Sanitary and Ship Canal between mile marker 296 and mile marker 296.7. Enforcement will occur from 7 a.m. through 1 p.m. and 3 p.m. to 5 p.m. from November 18, 2019 to November 22, 2019. During the enforcement period, no vessel may transit this regulated area without approval from the Captain of the Port Lake Michigan or a designated representative. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port Lake Michigan, or an on-scene representative.

This notice of enforcement is issued under the authority of 33 CFR 165.930 and 5 U.S.C. 552(a). In addition to this publication in the **Federal Register**, the Captain of the Port Lake Michigan will also provide notice through other means, which will include Broadcast Notice to Mariners, Local Notice to Mariners, distribution in leaflet form, and on-scene oral notice. Additionally, the Captain of the Port Lake Michigan may notify representatives from the maritime industry through telephonic and email notifications. If the Captain of the Port or a designated representative determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area. The Captain of the Port Lake Michigan or a designated on-scene representative may be contacted via Channel 16 or at (414) 747–7182.

Dated: November 1, 2019.

Thomas J. Stuhlreyer,

Captain, U.S. Coast Guard, Captain of the Port, Lake Michigan.

[FR Doc. 2019–24821 Filed 11–14–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 206

[Docket ID FEMA–2008–0005]

RIN 1660–AA18

Disaster Assistance-Federal Assistance to Individuals and Households

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Under the authority of section 408 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, the Federal Emergency Management Agency provides financial assistance to individuals and households after a Presidentially-declared major disaster or emergency. This rule finalizes, without change, current interim regulations which establish the requirements and procedures for the Individuals and Households Program.

DATES: This rule is effective December 16, 2019.

FOR FURTHER INFORMATION CONTACT: Mark Millican, FEMA, Individual Assistance Division, 500 C Street SW, Washington, DC 20472–3100, (phone) 202–212–3221 or (email) *FEMA-IA-Regulations@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 408 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) provides the Federal Emergency Management Agency (FEMA) the authority to administer the Individuals and

Households Program (IHP). *See* 42 U.S.C. 5174. Through the IHP, FEMA provides financial and/or direct assistance to help survivors recover from Presidentially-declared emergencies and major disasters. This help may be in the form of Housing Assistance and/or Other Needs Assistance, which includes personal property losses, medical, dental, funeral, child care, transportation, and other miscellaneous expenses.

Specifically, FEMA provides the following types of Housing Assistance:

Temporary Housing: Financial assistance is available to rent a different place to live for a limited period of time. If housing resources are not available and the applicant is unable to make use of FEMA-provided financial assistance, FEMA may provide direct assistance in the form of a manufactured housing unit.

Housing Repair: Financial assistance is available to homeowners to repair disaster damage to their primary residence. Assistance is only available to repair damage that is not covered by insurance. The goal is to make the damaged home safe, sanitary, and functional.

Housing Replacement: Financial assistance is available to homeowners to replace their primary residence if it was destroyed in the disaster. Assistance is only available for damage that is not covered by insurance.

Permanent and Semi-Permanent Housing Construction: In exceptional circumstances, FEMA is authorized to provide permanent and semi-permanent housing construction. If FEMA exercises its discretion to offer this form of disaster assistance, FEMA may provide financial assistance for the construction of a home or may construct the new permanent or semi-permanent housing unit for an individual or household. FEMA may provide this type of assistance only in insular areas outside the continental United States and in other locations when alternative housing resources are not available and no other types of temporary housing assistance are available, feasible, or cost-effective. Assistance is provided only for damage that is not covered by insurance.

44 CFR part 206, subparts D and F regulate the types of IHP assistance, the eligibility requirements for assistance, and the procedures for obtaining assistance.

On September 30, 2002, FEMA published an interim final rule in the **Federal Register**. *See* 67 FR 61446.[1] The interim final rule implemented new statutory authority provided from section 206 of the Disaster Mitigation Act of 2000, Public Law 106–390 (DMA 2000). Section 206 of the DMA 2000 consolidated and streamlined the provision of assistance to individuals, which FEMA previously administered under two separate assistance programs: (1) The Temporary Housing Assistance Program and (2) the Individual and Family Grant Program. Specifically, the interim final rule provided a framework for the new consolidated IHP in 44 CFR 206.110–206.120, as follows:

- Section 206.110 provided a broad overview of the new consolidated program.
- Section 206.111 provided the definitions for terms used throughout sections 206.110–120.
- Section 206.112 provided information on the registration period for the IHP.
- Section 206.113 provided the eligibility factors that individuals must meet in order to qualify for the IHP.
- Section 206.114 provided criteria for continued assistance in the IHP.
- Section 206.115 provided the appeals process and protocols for the IHP.
- Section 206.116 provided information on when and how FEMA would seek recovery of funds from IHP recipients.
- Section 206.117 provided information on the types of housing assistance as well as the eligible costs that are covered under the IHP.
- Section 206.118 provided the procedures that FEMA would follow if FEMA decides to sell temporary housing units that were purchased under 206.117(b)(1)(ii), temporary housing, or direct housing.
- Section 206.119 provided the process for individuals to be eligible to receive financial assistance to address other disaster-related needs.
- Finally, Section 206.120 provided the process and options for States when delivering financial assistance to address other disaster-related needs.

On April 3, 2009, FEMA published a final rule that provided technical, organizational, and conforming amendments to Title 44 of the CFR to reflect the current organization and procedures of FEMA. *See* 74 FR 15328. The final rule had no substantive effect on the regulated public and corrected organization names and addresses, updated Information Collection Approval Numbers issued by the Office of Management and Budget (OMB), removed the text of an Executive Order that was repealed, and made other technical and editorial corrections throughout Title 44. Specifically, in 44 CFR 206.110, 206.111, 206.112, 206.115, 206.117, and 206.120, FEMA updated the titles of various FEMA leadership positions as well as updated the term ''FEMA Office of Inspector General'' to ''DHS Office of Inspector General'' to reflect that FEMA became a component of the Department of Homeland Security in 2003.

On July 30, 2012, FEMA published a notice of proposed rulemaking (NPRM), which addressed the public comments received on the 2002 interim final rule related to housing repair and replacement, the provisions for which are found at 44 CFR 206.117. *See* 77 FR 44562. In addition, FEMA proposed four separate sets of changes in the NPRM. First, FEMA proposed revisions to the interim rule to respond to public comments received on the 2002 interim rule. Second, FEMA proposed changes that were intended to restate the existing requirements more clearly and in greater detail without substantively changing the underlying requirements. Third, consistent with statutory amendments in the Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA), FEMA proposed removing the housing repair and replacement subcaps which previously limited housing repair assistance to $5,000 and housing replacement assistance to $10,000. Finally, also consistent with statutory amendments in PKEMRA, FEMA proposed adding the term ''semi-permanent'' and removing the term ''remote'' with respect to the eligibility requirements for housing construction pursuant to PKEMRA.

On November 7, 2013, FEMA published a final rule that finalized the NPRM without change. *See* 78 FR 66852.

II. FEMA's Response to 2003 IHP Implementation Review Report

In February 2003, during the comment period for the Interim Final Rule, FEMA held a meeting with representatives from the five States who first implemented the IHP to identify the best practices and problems or issues that needed corrective actions. An IHP Implementation Review Report was prepared, which outlined the issues discussed and recommendations. None of the issues discussed were specifically pertinent to this rulemaking.

The general topics discussed and the recommendations were related to:

1. The business rules and functionality for the National Emergency Management Information System (NEMIS), which FEMA uses to

[1] FEMA published a correction to the interim final rule on October 9, 2002. *See* 67 FR 62896.

process applications for disaster assistance;

2. Internal and external communications, to include FEMA Helpline numbers and printed Applicant Guides;

3. Addressing unmet needs of disaster survivors through referrals to voluntary agencies;

4. Financial and grants management regarding internal billing processes and procedures;

5. Training needs for field staff administering the program; and

6. Policy development.

All of these topics focused primary on procedural and other aspects of IHP that were beyond the scope of the interim final rule and were addressed in separate actions, such as developing policies, training courses, fact sheets and handouts, or standard operating procedures. Therefore, FEMA is not addressing these issues and recommendations in this final rule.

III. Discussion of Comments Received on 2002 Interim Final Rule

In response to the 2002 interim final rule, FEMA received written comments from five States: Texas, Maine, Washington, New York, and Virginia. This section describes the comments received, as well as FEMA's responses to the public's input.

Comments Regarding Duplication of Benefits (44 CFR 206.110(h))

Section 206.110(h) in the interim final rule addresses duplication of benefits. Under this section, FEMA will not provide assistance under IHP when any other source has already provided such assistance or when such assistance is available from any other source. The section also states that in the instance of insured applicants, FEMA will provide assistance only when:

1. Payment of the applicable benefits are significantly delayed;

2. applicable benefits are exhausted;

3. applicable benefits are insufficient to cover the housing or other needs; or

4. housing is not available on the private market.

Three State agencies (from Washington, Virginia, and Maine) commented on this section. All three State agencies commented that the term ''significantly delayed'' should be defined in the regulation so that it is applied consistently and equitably and to avoid confusion and undue hardship while the term is being debated at the time of a disaster. The commenters stressed that the definition should be in the regulation as opposed to a policy.

Two State agencies (Washington and Maine) commented that if the estimated damage is below the deductible of the insurance policy, the applicant should not have to wait for a formal denial from the insurance company in order for FEMA to process the application, especially since insurance companies are slow to provide damage reports and produce decisions on eligibility. Rather, the regulation should allow an applicant to certify to FEMA that the estimated damage is below the maximum allowable repair assistance award and to provide a copy of the hazard insurance declaration page that clearly shows the damage is below the insurance deductible. The commenters proposed that if at the time of disaster the applicant estimates the damage to be below the insurance deductible, the applicant should be allowed to produce a copy of the declaration page or policy at the time of inspection in order to receive immediate assistance. In addition, two State agencies (Washington and Virginia) recommended modifying the regulation text to provide assistance to applicants immediately if they produced an insurance declaration page as proof of the limits of the policy.

In support of its comment, a Washington State agency described how, following an earthquake affecting 22 counties in that State, most of the homes had less than $10,000 damage, and since the homes were valued in excess of $100,000, the damage was below the earthquake insurance deductible of 10 percent. The commenter described how the applicant had to send in an insurance denial before FEMA would process the application and that later, FEMA changed its policy and asked the applicant to send in the declaration page of the earthquake policy, if damage was below $10,000. The commenter stated that this further confused the affected public. The commenter concluded that when applicants have to wait for an insurance denial before FEMA will consider their application, the applicants assume falsely that they would have been better off if they had not had the insurance, which has the unintended consequence of applicants dropping their insurance coverage.

Finally, the commenters on the insurance coverage provision also suggested that if FEMA makes the requested changes, FEMA should also make conforming changes to 44 CFR 206.113(a).

FEMA's Response

The three State agencies that commented that the term ''significantly delayed'' should be defined in the regulation were in error. The term ''significantly delayed'' was defined in the interim final rule at 44 CFR 206.111 and used at 44 CFR 206.110(h) and 44 CFR 206.113(a)(3). The term ''significantly delayed'' is defined in the interim final rule as more than 30 days.

With respect to the request that FEMA amend the regulation to allow for an applicant to certify to FEMA that the estimated damages are below the maximum allowable repair assistance award and to provide a copy of the hazard insurance declaration page that clearly shows the damage is below the insurance deductible, FEMA has concluded that applicants are not qualified to objectively estimate the total cost of damages, and therefore are not qualified to certify that the estimated cost is below their deductible. Therefore, FEMA did not make any changes based on this comment.

In addition, prior to DMA 2000, FEMA accepted declaration pages from applicants to support their claims for assistance. However, an unintended consequence of this was that applicants were asking their insurance companies for a copy of their declaration page. In turn, the insurance companies classified the applicants' inquiries as claims against their policies, so in some cases, the applicants' insurance premiums were increased. After DMA 2000, FEMA made a policy determination to stop accepting declaration pages from applicants to support their claims for assistance. For this reason as well, FEMA did not make any changes based on this comment.

With respect to the comment from the Washington State agency, FEMA notes that if the applicant has filed a claim with their insurance provider and, through no fault of their own, the coverage has been delayed for 30 days or more and the person has agreed to pay FEMA back when their insurance proceeds arrive, FEMA can provide assistance up to the maximum IHP award. For fiscal year 2020, the IHP maximum award is $35,500 for housing assistance and $35,500 for other needs assistance. 84 FR 55323, Oct. 16, 2019; *see* 44 CFR 206.113(a)(3). In addition, if the applicant's insurance proceeds are less than what FEMA can authorize and the proceeds are insufficient to cover the necessary expenses or serious needs, FEMA can provide the difference up to the maximum award. *See* 44 CFR 206.113(a)(4). Otherwise, FEMA would be competing with the applicant's insurance company to see which entity could issue assistance the fastest. FEMA has to allow the insurance company time to process the applicant's claim.

FEMA does not agree that applicants would have been better off if they had

not had insurance. The Stafford Act only allows FEMA to issue a maximum amount of assistance, which is usually much less than the amount of insurance coverage for which an applicant could insure their dwelling. IHP provides financial assistance and, if necessary, direct assistance to eligible individuals and households who, as a direct result of an emergency or major disaster, have uninsured or under-insured necessary expenses and serious needs, and are unable to meet such expenses or needs through other means. IHP's purpose is not to make an applicant ''whole again.'' FEMA's assistance is intended to help applicants on the road to self-sufficiency. Therefore, FEMA did not propose any changes to the regulations based upon this comment.

Comments Regarding Conditions of Ineligibility (44 CFR 206.113(b))

The interim final rule at 44 CFR 206.113(b)(9) indicates business losses are ineligible for IHP grant assistance. One State (Texas) commented that there should be an exception to the rule forbidding IHP grant assistance for business losses. The State proposed that the exception should allow IHP to provide grants for the loss of uninsured work tools for self-employed individuals who are denied loan assistance from the U.S. Small Business Administration (SBA) for financial reasons. The commenter noted that under current regulations, self-employed individuals who suffer work tool loss, and are ineligible for SBA loans, receive no assistance from IHP for this significant loss, and therefore, they fall through the cracks of the recovery program.

FEMA's Response

Section 408(e) of the Stafford Act limits financial assistance to medical, dental, child care, funeral expenses, personal property, transportation, and other necessary expenses or serious needs resulting from the major disaster. Financial assistance for ''personal property'' losses provides assistance to repair or replace personal property damaged or destroyed due to a disaster.[2] Financial assistance for ''other necessary expenses'' provides assistance to households with certain disaster-caused miscellaneous expenses; eligible items must be purchased or rented after the incident to assist with the applicant's disaster recovery.[3] FEMA does allow for assistance to replace essential tools, supplies, and equipment owned pre-disaster that are required by an employer as a condition for employment.[4] If a self-employed individual's tools are destroyed due to a disaster, FEMA considers the tools as property of the business and not the individual and thus a business loss. The Small Business Administration Office of Disaster Assistance's provides low interest disaster loans to businesses of all sizes, private non-profit organizations, homeowners, and renters to repair or replace real estate, personal property, machinery and equipment, inventory and business assets that have been damaged or destroyed in a declared disaster.[5] Section 312 of the Stafford Act prohibits duplication of benefits for losses incurred as a result of a major disaster. Since the SBA provides assistance for business related losses, FEMA structured the IHP to provide assistance to individuals and households and not businesses, and thus FEMA chose to not make any changes to the regulations based on this comment.

Conditions Regarding Appeals (44 CFR 206.115(b))

Section 206.115 allows for applicants to appeal any determination of eligibility under 44 CFR part 206, subpart D. Section 206.115(b) provides that ''appeals must be in writing and explain the reason(s) for the appeal.'' One State (Washington) recommended that FEMA publish an email address for use in filing appeals, as this would expedite the appeals process, would reduce the possibility of lost regular mail, and would speed up the process of passing misdirected appeals to the right agency.

FEMA's Response

FEMA does not provide the address in 44 CFR 206.115(b) since the address to submit appeals may change and FEMA would not want applicants to have to wait for the publication of a document in the **Federal Register** before they would have the updated address to submit their appeal. Instead, FEMA provides applicants with the address that they may submit an appeal to in FEMA's denial letter. FEMA does not provide an email address in the denial letter, as FEMA does not have a secure system in place that would allow appeals to be emailed to FEMA. The only secure server FEMA has in place that can accommodate applicant appeals is the system handling applications for FEMA disaster assistance. If an applicant creates an online disaster assistance account, they can submit an appeal ''electronically'' by uploading appeal documentation into their file.

Comments Regarding Moving and Storage (44 CFR 206.119(c)(5))

The proposed rule, in 44 CFR 206.110(c)(5), provided for financial assistance for necessary expenses and serious needs related to moving and storing personal property ''away from the threat of damage including the evacuation'' of such property. In contrast, the interim final rule, in 44 CFR 206.119(c)(5), provided for financial assistance for necessary expenses and serious needs related to moving and storing personal property ''to avoid additional disaster damage.'' Four State agencies (Virginia, New York, Texas, and Washington) commented on this provision, stating that financial assistance should be provided for pre-disaster preventative moving and storage and not only for moving and storage of property after a disaster has occurred. Several commenters noted that the restriction on paying for pre-disaster moving and storage was inconsistent with the Federal and State philosophy of promoting and supporting hazard mitigation measures and that the people should be encouraged to move personal property out of flood zones, if they have time to do so. One commented that it was most desirable that proactive actions be taken to avoid serious harm or injury to person or property.

The commenters stated that the cost of moving and storage was much less than the cost of replacing personal property. One commented that the concept of not paying for taking preventive measures to reduce the potential loss is in direct contrast to the ''insurance model,'' where individuals who sustain losses or may incur additional losses are required to take necessary and effective action to prevent or mitigate further losses and that the reimbursement of expenses incurred to minimize prospective losses prior to or during a disaster would seem to be prudent and should be encouraged and rewarded. The commenter stated that it was inconsistent to not reimburse an applicant for moving items out of harm's way prior to a disaster and then make them purchase mandatory flood insurance coverage for items that could have been safeguarded.

[2] FEMA, Individuals and Households Program Unified Guidance, FP 104–009–3, September 30, 2016, at 105, available at *https://www.fema.gov/media-library/assets/documents/124228.*

[3] Id. at 102.

[4] *Id.* at 107.

[5] Small Business Administration, A Reference Guide to the SBA Disaster Loan Program, May 2015, at 1, available at *https://www.sba.gov/sites/default/files/files/SBA_Disaster_Loan_Program_Reference_Guide.pdf.*

FEMA's Response

Section 408(e)(2) of the Stafford Act provides that financial assistance may be provided to address personal property, transportation, and other necessary expenses or serious needs resulting from the major disaster. FEMA interpreted Section 408(e)(2) in 44 CFR 206.119(c)(5) to provide financial assistance under ONA to pay for the cost of storage of personal property while repairs are being made to the primary residence and the cost of returning the property to the applicant's primary residence. FEMA has provided further guidance that eligible expenses for moving and storage assistance include the following expenses: Costs for commercial moving labor, moving truck rental fee, fuel for the rental vehicle, costs for tape and boxes, storage unit fees, and associated sales taxes.[6]

With respect to comments stating that the restriction on paying for pre-disaster moving and storage is inconsistent with the Federal and State philosophy of promoting and supporting hazard mitigation measures, FEMA believes that even if it were to remove the restriction and begin paying for pre-disaster moving and storage expenses it would have limited affect, as it would only apply sporadically and affect a small population of disaster survivors. This is because pre-disaster moving and storage expenses would only apply to specific types of disasters that have advance warning such as hurricanes and lava flows. Unexpected disasters such as earthquakes and tornados would not be eligible for pre-disaster moving and storage expenses because those events occur without sufficient warning to permit sufficient time to move and store. In addition, FEMA's system for processing applications for IHP accepts expenses that occurred post major disaster declaration date. Allowing moving and storage expenses pre-disaster declaration date is an administrative challenge and would require system changes. For these reasons, FEMA has chosen, at this time, to continue to limit moving and storage assistance to assistance provided after the disaster has occurred while repairs are being made to the primary residence. However, FEMA is taking the commenter's suggestion under advisement and it will conduct a policy review to evaluate a possible future change to allow moving and storage expenses pre-disaster declaration date.

With respect to comments stating that the cost of moving and storage was much less than the cost of replacing personal property, FEMA also notes that the insurance industry generally does not reimburse for pre-disaster, preventative moving and storage. In addition, the insurance industry requires individuals who sustain losses or may incur additional losses to take necessary and effective action to prevent or mitigate further losses. The insurance industry generally does not require prevention or mitigation before the loss occurs.

Comments Regarding Ineligible Costs (44 CFR 206.120(f)(3))

As discussed in the NPRM and changed by the interim final rule, the Other Needs Assistance (ONA) provision of the IHP may be administered one of three ways: (1) Exclusively by FEMA, (2) administered by the State with substantial FEMA assistance, or (3) by the State with minimal FEMA participation. If the State administers ONA, it may request a grant from FEMA that it uses to administer assistance to individuals and households in the State. In accordance with section 408(f)(1)(B) of the Stafford Act, a State that receives an ONA grant may expend not more than 5 percent of the amount of the grant for administrative costs. These administrative costs typically include conducting grants management oversight; generating financial status reports, weekly program status reports, and other accounting documents; maintaining records; and conducting audits.

Under the terms of 44 CFR 206.120(f)(3), funds provided to the State for administrative costs cannot be used to pay regular time for State employees but may be used to pay overtime for those employees. Three of the State agencies that commented on the rule (Texas, Washington, and New York) disagreed with this provision. One commenter stated that FEMA had arbitrarily implemented a rule that runs contrary to the definition of eligible costs in OMB Circular A–87, Attachment A, General Principles for Determining Allowable Costs. The commenter stated that staff costs, whether they are incurred by an incumbent State employee or newly hired person, should be an eligible expense against grant management if the employee spends most of his/her available hours managing the grant.

Another commenter stated that because overtime is an allowed expense by 206.120(f)(3),[7] and thus recognized as an identifiable and specific function which fully benefits IHP/ONA, regular time should be allowed since it is also an identifiable and specific function which fully benefits IHP/ONA. The commenter also stated that funding the regular time of State employees with another funding source would contradict OMB Circular No. A–87, Attachment A, C.3.c., which addresses overcoming funding deficiencies for Federal grant awards.

Commenters stated that some employees involved in IHP/ONA administration devote 100 percent of their time to the management of the disaster processing operation, and for those that perform other tasks in addition to grant management, any sizeable disaster will require hiring additional staff to backfill the other duties that the grant manager no longer has time to do.

A commenter stated that the current rule, as written, runs contrary to a State's effort to remain involved in ONA and that considerable time and effort has been expended in order to train State staff to be ready and able to respond effectively to disaster declarations. According to the commenter, the current rule encourages States to hire a temporary person to manage the grant, thus allowing their salary to be a legitimate cost against the 5 percent administrative fee; however, hiring someone who knows nothing about the IHP, which needs to be up and running within hours of a declaration, is not justifiable.

FEMA's Response

The 2002 interim final rule was not contrary to the definition of eligible costs in OMB Circular A–87. On September 30, 2002, the date that FEMA promulgated the interim final rule (*see* 67 FR 61446), the applicable version of OMB Circular A–87 was the version published in the **Federal Register** on May 17, 1995. *See* 60 FR 26484. The 1995 OMB Circular A–87, Attachment A, E.2.a., states that typical direct costs that are chargeable to Federal awards include compensation for employees for the time devoted and identified specifically to the performance of those awards. However, OMB Circular A–87 does not prohibit FEMA from making

[6] FEMA, Individuals and Households Program Unified Guidance, FP 104–009–3, September 30, 2016, at 111, available at *https://www.fema.gov/media-library/assets/documents/124228.*

[7] The commenter referenced 44 CFR 206.120(e)(3). FEMA construes the citation as a reference to 44 CFR 206.120(f)(3), because section 206.120(e)(3) does not exist and 44 CFR 206.120(f)(3) states that ''Funds provided to the State for the administrative costs of administering Other Needs assistance shall not be used to pay regular time for State employees, but may be used to pay overtime for those employees.''

these types of direct costs ineligible through the regulatory process. *See* 1995 OMB Circular No. A–87, Attachment A, C.1d.

With respect to the commenter's statement that funding the regular time of State employees with another funding source would contradict the 1995 OMB Circular No. A–87 C.3.c., FEMA construes the citation as a reference to the 1995 OMB Circular No. A–87, Attachment A, C.3.c., as the referenced cite, C.3.c., does not exist in the main portion of the 1995 OMB Circular No. A–87. The interim final rule at 44 CFR 206.120(f)(3) does not contradict the 1995 OMB Circular No. A–87, Attachment A, C.3.c., as the regular time of State employees would be funded by the State and would not be charged to other Federal awards to overcome funding deficiencies. FEMA made a program determination to reimburse States that hire additional personnel for the grant because in such cases the costs for the additional personnel hired are directly linked to the management of the IHP/ONA grant award. FEMA determined that it would reimburse the State for the costs for these additional State employees because their salaries are not covered under previously appropriated funds in a State's budget and they were hired simply to work on the management of the IHP/ONA grant award. For the same reasons, 44 CFR 206.120(f)(3) does not contradict the 1995 OMB Circular No. A–87, Attachment A, C.3.c.

Since the interim final rule was promulgated, OMB has issued two additional versions of OMB Circular A–87, which have superseded the previous versions. *See* 69 FR 25970 and 78 FR 78590. The 2004 OMB Circular A–87 version was merely a revision, and while the citations were updated, the language was not changed. In 2013, OMB issued final guidance that superseded and streamlined requirements from OMB Circulars A–21, A–87, A–110, and A–122 (which have been placed in OMB guidance); Circulars A–89, A–102, and A–133; and the guidance in Circular A–50 on Single Audit Act follow up. *See* 78 FR 78590. The purpose of this consolidation was to provide the aforementioned circular in a streamlined format that aims to improve both clarity and accessibility.

Comments Regarding Ineligible Costs (44 CFR 206.120(f)(3)) and Federalism

One commenter also added that the interim final rule appears to be a subtle attempt to encourage the States to let FEMA administer the grants. The commenter stated that the rule may, therefore, have federalism implications.

FEMA's Response

As discussed under the Federalism heading of the preamble, a rule has federalism implications if it has a substantial direct effect on the States, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. This regulation clearly leaves the decision whether to administer (or apply for) ONA to the States. ''Subtle encouragement'' to participate voluntarily in a Federal program, whether intended or not, does not rise to the level of a rule with federalism implications. The regulatory text in question does not require States to participate in the program, mandate that FEMA administer the program, prohibit States from administering the program, or limit the policymaking discretion of the States with respect to whether they may or may not administer the program. States are free to administer the grants; however, FEMA will not fund the regular salaries of State employees, for the reasons stated above.

Comments Regarding Recovery of Other Needs Assistance Funds (44 CFR 206.120(f)(5))

Section 206.120(f)(5) requires the States to recover ONA funds from applicants who obtained the funds through fraud, who expended the funds for unauthorized items or services, who expended the funds for items for which assistance is received from other means, and from applicants to whom the award was made in error. Four State agencies (Texas, Washington, Maine, and New York) commented that the States should not be responsible for recovering ONA funds when the recovery is necessary due to FEMA error, for example when a grant is issued erroneously by FEMA's automated determination process. One State agency proposed that, since many States use the ''AUTO–D'' option, which is based on the FEMA inspection reports and business rules set up in NEMIS, the following language should be added to 44 CFR 206.120(f)(5): ''FEMA will be responsible for recovering assistance awards from applicants when an award has been mistakenly made as a result of a FEMA processing error.'' The commenter added that the State administrative ''cost to recover funds runs two to three times more than the cost of issuing an award. Under the current FEMA policy, the administrative costs are deducted from the total Federal outlay, which means the States are not compensated (five percent administrative costs) for moneys recovered.'' The commenter noted that requiring the States to recover award moneys for Federal mistakes results in use of State funds to correct Federal errors, which is punitive to the States.

FEMA's Response

FEMA inserted 44 CFR 206.120 into the interim final rule to address the financial management principles that FEMA would use to implement the ONA portion of the IHP. Even before FEMA published the proposed IHP rule, a number of States had expressed a desire to actively participate in the administration of IHP. The comments that FEMA received on both the proposed and interim final rule indicated that the States wanted opportunities to be active partners in the administration of the new program. One component in the administration of the IHP is the recovery of funds that were issued in error. Federal agencies are required to take action to identify and recover improper payments, regardless of whether the payments were made in error or obtained by fraud.[8] In addition, by statute, applicants must return funds to FEMA when the assistance provided by FEMA duplicates assistance from another source.[9] And the generally applicable IHP regulations, which apply regardless of which entity administers IHP, require applicants to return funds when such funds were provided in error, were spent inappropriately, or were obtained through fraudulent means.[10] When a State is administrating the ONA portion of the IHP, FEMA provides a grant to the State, territorial, or Tribal government and they are responsible for all tasks associated with the administration of ONA. The State, territorial, or Tribal government provides assistance to applicants, and FEMA is responsible for reimbursing the State, territorial, or Tribal government for its portion of the cost share. The State, territorial, or Tribal government may utilize 5 percent of the grant toward administrative costs, including the costs of reimbursement. Because the State, territorial, or Tribal government are the entities who made the decisions regarding whether an applicant was eligible for ONA funds and have the records regarding who was awarded ONA funds, the State, territorial, or Tribal government are ultimately the party that must be responsible for recovering funds that were issued in error.

[8] The Debt Collection Act of 1996, Public Law 104–34; 31 U.S.C. 3711(a).

[9] Section 312(c) of the Stafford Act, 42 U.S.C. 5155(c); 44 CFR 206.191.

[10] 44 CFR 206.116(b).

Additionally, as a result of cost-share requirements, 25 percent of the funds that were issued in error are actually State funds that need to be returned to the State. Thus, the State can recover the funds, subtract their portion of funds, and return the remaining 75 percent to the Federal Government.

Comments Regarding Flood Insurance Purchase Requirement (44 CFR 206.110(k)) and Group Flood Insurance Policy (44 CFR 206.119(d))

The Flood Disaster Protection Act of 1973, as amended, requires that individuals or households that are located in a Special Flood Hazard Area (SFHA) may not receive Federal assistance for National Flood Insurance Program (NFIP) insurable real and/or personal property damaged by a flood unless the community in which the property is located is participating in the NFIP. *See* 42 U.S.C. 4001–4129. In addition, the National Flood Insurance Reform Act of 1994 and the Riegle Community Development and Regulatory Improvement Act of 1994 state that no Federal disaster assistance may be provided to a person for damage to any personal or residential property who has received flood disaster assistance that was conditioned on the person first having obtained flood insurance and subsequently failed to obtain and maintain flood insurance as required. See 42 U.S.C. 5154a. Pursuant to the flood insurance purchase requirement, individuals and households must buy and maintain flood insurance as a condition of receiving Federal assistance. For purposes of IA, FEMA interprets financial assistance to mean assistance to an individual or household to buy, receive, build, repair, or improve insurable portions of a home and/or to purchase or repair insurable contents. *See* 44 CFR 206.110(k).

Individuals identified by FEMA as eligible for ONA under section 408 of the Stafford Act as a result of flood damage caused by a Presidentially-declared major disaster and who reside in a special flood hazard area may be included in a Group Flood Insurance Policy (GFIP) established under the NFIP. *See* 44 CFR 206.119(d). The GFIP is a policy that is established for each disaster declaration that results from flooding and authorizes the provision of Individual Assistance. FEMA or the State will withhold a portion of ONA funds for such individuals and provide it to the NFIP on behalf of individuals and households who are eligible for coverage. Payments to cover the premium amount for each applicant are paid for a 3-year policy term. The master GFIP policy term is for 36 months and begins 60 days from the date of the disaster declaration. However, individual coverage becomes effective 30 days following the NFIP's receipt of the applicant's name and premium payment from the State, Territory, Tribal government, or FEMA.

Three State agencies (Washington, Virginia, and Texas) commented on the requirement that individuals and households must purchase flood insurance when their GFIP grant ends. Washington and Virginia stated that the requirement to maintain the policy places a disproportionate burden on the poor, as the poor were more likely to buy property in SFHAs because it is the least expensive property in a community, and that the cost of GFIP renewal for such individuals was cost-prohibitive, given their limited resources. Texas stated that, since the penalty for failure to purchase and maintain flood insurance, which is a condition of IHP, is a denial of future disaster assistance, it would be imprudent not to continue to provide GFIP coverage for low income disaster victims.

Three State agencies (Maine, Washington, and Virginia) commented that FEMA should consider changing the GFIP requirement for people who cannot pass an SBA income test. Maine expressed concern that the individuals would become disenfranchised from assistance following the expiration of their GFIP grant and that, unless the financial situations of such individuals improved dramatically, it was unlikely that such individuals would either qualify for SBA programs or be able to pay an NFIP premium following the expiration of the GFIP grant. Virginia also commented that if an individual fails the SBA income test they should be subsidized by a formula based system.

FEMA's Response

In the proposed rule, FEMA proposed the elimination of the GFIP. *See* 67 FR 3415. As discussed in the interim final rule, FEMA received comments from States which supported the continuation of the GFIP. *See* 67 FR 61449. The States stated that the basis for their support of the program related to the fact that disaster survivors who qualified for Individual and Family Grant assistance (the precursor program to the IHP) generally had low incomes and were not as able to afford to pay flood insurance premiums as other disaster survivors. *See* 67 FR 61449. Because the penalty for failing to purchase and maintain flood insurance as a condition of receiving disaster assistance under the old Individual and Family Grant Program and under the new IHP is a denial of future disaster assistance, most of the States that commented on FEMA's proposal believed that it would be imprudent not to continue providing GFIP coverage for low income disaster survivors.

FEMA retained the GFIP in the interim final rule based upon the comments FEMA received on the proposed rule as well as the requirement from the National Flood Insurance Reform Act of 1994 and the Riegle Community Development and Regulatory Improvement Act of 1994 (*See* 42 U.S.C. 5154a). But some States questioned the requirement to maintain flood insurance, arguing that it places a disproportionate burden on the poor, since the poor are more likely to buy property in special flood areas because they are the least expensive properties in a community, and that the cost for such individuals is too high. Also, the Stafford Act requires the purchase and maintenance of flood insurance as a condition of receiving future disaster assistance in certain circumstances. *See* 42 U.S.C. 5154a. Therefore, FEMA does not have the discretion to waive the flood insurance requirement. To assist applicants with maintaining flood insurance, as mentioned above, FEMA provides all eligible applicants with GFIP for 3 years. *See* 44 CFR 206.119(d).

Comments Regarding Executive Order 12898, Environmental Justice

Two State agencies (Washington and Virginia) commented generally that the interim final rule would ''discriminate covertly'' against the poor. Specifically, these two commenters stated that the housing repair cap of $5,000 and the housing replacement cap of $10,000 have a negative impact on low-income disaster survivors.

FEMA's Response

FEMA does not believe that the interim final rule discriminates covertly against the poor. For instance, the interim final rule assisted the poor by retaining the GFIP.

The two comments that FEMA received regarding the housing repair and replacement caps were addressed in the final rule published on November 7, 2013, that removed the caps.

IV. Final Rule

FEMA is finalizing the interim final rule implementing 44 CFR 206.110–120 published on September 30, 2002, (67 FR 61446), with the corrections published on October 9, 2002, (67 FR 62896), the technical amendments to 206.110, 206.111, 206.112, 206.115, 206.117, and 206.120 published on

April 3, 2009, (74 FR 15328), and the amendments to 206.117 published on November 7, 2013, (78 FR 66852), without change.

V. Regulatory Analysis

A. Executive Order 12866, Regulatory Planning and Review, Executive Order 13563, Improving Regulation and Regulatory Review and Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs'') directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. *See* OMB's Memorandum ''Guidance Implementing Executive Order 13771, Titled 'Reducing Regulation and Controlling Regulatory Costs''' (April 5, 2017).

This final rule will result in no changes to the IHP and FEMA does not anticipate any additional costs. FEMA is not requiring applicants to perform any additional tasks, fill out any new forms, or provide any additional information. It is anticipated that the cost to applicants will not change as a result of this rule. FEMA is not changing the parameters of the program in any way so there is no expectation that the number of applications processed by FEMA would be altered. As such, FEMA's workload will not be impacted.

The IHP provides financial and direct assistance to those who, as the result of a Presidentially-declared emergency or major disaster, have necessary expenses and serious needs they are unable to meet through other means. This aid may include temporary housing, aid to repair or replace housing, permanent or semi-permanent housing construction, and ONA, which provides financial assistance for personal property losses, medical, dental, funeral, child care, transportation, and other miscellaneous expenses. These services and the benefits derived from them are not being altered by this final rule and will continue to exist at their current levels. Since there are no changes to the amount or type of assistance available, there will correspondingly be no change in the benefits currently derived from the IHP.

Similarly, this final rule will not change the number of eligible applicants or the amount of funds expended per applicant. This rule also has no anticipated impact on transfers.

This rule finalizes an interim final rule and addresses outstanding comments received on the September 30, 2002 interim final rule. This final rule makes no changes to the IHP either in response to or independent of those comments. FEMA does not anticipate any changes to the associated costs, benefits, or transfers from this final rule.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), FEMA must consider the impact of this proposed regulation on small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. When the Administrative Procedure Act requires an agency to publish a notice of proposed rulemaking under 5 U.S.C. 553, the RFA requires a regulatory flexibility analysis for both the proposed rule and the final rule if the rulemaking could ''have a significant economic impact on a substantial number of small entities.''

This final rule concerns the provision of Federal assistance to individuals and households after a Presidentially-declared emergency or major disaster. Individuals and households are not classified as small entities. A household is defined at 44 CFR 206.111 as ''all persons (adults and children) who lived in the pre-disaster residence who request assistance under this subpart, as well as any persons such as infants, spouse or part-time residents who were not present at the time of the disaster, but who are expected to return during the assistance period.'' This rule does not directly regulate any small entities.

Additionally, while this rule is addressing comments from the September 30, 2002 interim final rule, it is making no changes and imposes no direct costs.

During the public comment period on the January 23, 2002, NPRM, FEMA did not receive any comments contrary to the Regulatory Flexibility Analysis certification provided at that time.

Accordingly, pursuant to section 605(b) of the RFA, 5 U.S.C. 605(b), the head of FEMA certifies this rule will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 658, 1501–1504, 1531–1536, 1571, pertains to any notice of proposed rulemaking which implements any rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) or more in any one year. If the rulemaking includes a Federal mandate, the Act requires an agency to prepare an assessment of the anticipated costs and benefits of the Federal mandate. The Act also pertains to any regulatory requirements that might significantly or uniquely affect small governments. Before establishing any such requirements, an agency must develop a plan allowing for input from the affected governments regarding the requirements. The Act exempts any regulation or proposed regulation that ''requires compliance with accounting and auditing procedures with respect to grants or other money or property provided by the Federal Government'' or ''provides for emergency assistance or relief at the request of any State, local, or tribal government or any official of a State, local, or tribal government.'' 2 U.S.C. 1503(4). FEMA finds this rule to be exempt from the Act under those provisions.

As reported in the 12866 section, FEMA has determined that this rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, nor by the private sector, of $100 million or more in any one year as a result of a Federal mandate, and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

D. National Environmental Policy Act

Under the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 42 U.S.C. 4321 *et seq.,* an agency must prepare an environmental assessment or environmental impact statement for any rulemaking that significantly affects the quality of the human environment. FEMA has determined that this rulemaking does not significantly affect the quality of the human environment and consequently has not prepared an environmental assessment or environmental impact statement.

Rulemaking is a major Federal action subject to NEPA. Categorical exclusion A3 included in the list of exclusion categories at Department of Homeland Security Instruction Manual 023–01–001–01, Revision 01, Implementation of the National Environmental Policy Act, Appendix A, issued November 6, 2014, covers the promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, and advisory circulars if they meet certain criteria provided in A3(a–f). This final rule finalizes an existing regulation without changing its environmental effect, which meets Categorical Exclusion A3(d).

E. Paperwork Reduction Act of 1995

FEMA has determined that this rule will not create a new collection of information or create a revision to an existing collection of information under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520. All information submitted by applicants seeking IHP housing assistance, including information submitted on appeal, is included in OMB-approved collections.

The following collections related to IHP have been approved by OMB under the following titles and control numbers: ''Disaster Assistance Registration,'' OMB control number 1660–0002, expiration date August 31, 2022, and ''Federal Assistance to Individuals and Households Program (IHP),'' OMB control number 1660–0061, expiration date May 31, 2020. There is no additional paperwork burden as a result of this final rule.

F. Privacy Act

Under the Privacy Act of 1974, 5 U.S.C. 552a, an agency must determine whether implementation of a proposed regulation will result in a system of records. A ''record'' is any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his/her education, financial transactions, medical history, and criminal or employment history and that contains his/her name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph. See 5 U.S.C. 552a(a)(4). A ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. An agency cannot disclose any record which is contained in a system of records except by following specific procedures.

FEMA, in partnership with other Federal agencies, hosts a single application and resource center at *http://www.disasterassistance.gov* that allows the public to apply for disaster assistance, benefits, and other services within FEMA and other Federal agencies. This application and resource center accepts personally identifiable information about IHP applicants seeking disaster related housing and other needs assistance. The application resource center is included in a Privacy Act System of Records entitled ''Disaster Recovery Assistance Files'' number ''DHS/FEMA–008'' which was published on April 30, 2013, in the **Federal Register** at 78 FR 25282. This final rule would not change the application materials received or result in a new collection of personally identifiable information about individuals.

G. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' 65 FR 67249, November 9, 2000, applies to agency regulations that have Tribal implications, that is, regulations that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Under this Executive Order, to the extent practicable and permitted by law, no agency shall promulgate any regulation that has Tribal implications, that imposes substantial direct compliance costs on Indian Tribal governments, and that is not required by statute, unless funds necessary to pay the direct costs incurred by the Indian Tribal government or the Tribe in complying with the regulation are provided by the Federal Government, or the agency consults with Tribal officials. This final rule would not significantly or uniquely affect the communities of Indian Tribal governments, nor would this rulemaking impose substantial direct compliance costs on those communities.

H. Executive Order 13132, Federalism

Executive Order 13132, ''Federalism,'' 64 FR 43255, August 10, 1999, sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action. The disaster assistance addressed by this final rule is provided to individuals and households, and would not have federalism implications.

I. Executive Orders 11988 and 11990, Floodplain Management and Protection of Wetlands

Executive Order 11988, ''Floodplain Management,'' 42 FR 26951, May 24, 1977, sets forth that each agency is required to provide leadership and take action to reduce the risk of flood loss, to minimize the impact of floods on human safety, health and welfare, and to restore and preserve the natural and beneficial values served by floodplains in carrying out its responsibilities for (1) acquiring, managing, and disposing of Federal lands and facilities; (2) providing Federally undertaken, financed, or assisted construction and improvements; and (3) conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities. In carrying out these responsibilities, each agency must evaluate the potential effects of any actions it may take in a floodplain; ensure that its planning programs and budget requests reflect consideration of flood hazards and floodplain management; and prescribe procedures to implement the policies and requirements of the Executive Order.

Before promulgating any regulation, an agency must determine whether the proposed regulations will affect a floodplain(s), and if so, the agency must

consider alternatives to avoid adverse effects and incompatible development in the floodplain(s). If the head of the agency finds that the only practicable alternative consistent with the law and with the policy set forth in Executive Order 11988 is to promulgate a regulation that affects a floodplain(s), the agency must, prior to promulgating the regulation, design or modify the regulation in order to minimize potential harm to or within the floodplain, consistent with the agency's floodplain management regulations and prepare and circulate a notice containing an explanation of why the action is proposed to be located in the floodplain.

The requirements of these Executive Orders apply in the context of the provision of Federal financial assistance relating to, among other things, construction and property improvement activities, as well as conducting Federal programs affecting land use. This final rule would not have an effect on land use, floodplain management, or wetlands. When FEMA undertakes specific actions in administering IHP that may have effects on floodplain management (*e.g.,* placement of manufactured housing units on FEMA-constructed group sites; permanent or semi-permanent housing construction; Multi-Family Lease and Repair; financial assistance for privately owned roads and bridges), FEMA follows the procedures set forth in 44 CFR part 9 to assure compliance with this Executive Order. The notice that is required by the Executive Order is provided separately at the time FEMA undertakes the specific action.

J. Executive Order 12898, Environmental Justice

Under Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' 59 FR 7629, February 16, 1994, as amended by Executive Order 12948, 60 FR 6381, February 1, 1995, FEMA incorporates environmental justice into its policies and programs. The Executive Order requires each Federal agency to conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that those programs, policies, and activities do not have the effect of excluding persons from participation in programs, denying persons the benefits of programs, or subjecting persons to discrimination because of race, color, or national origin. FEMA has incorporated environmental justice into its policies, programs, and activities.

The IHP regulations intentionally contain provisions that ensure they would not have a disproportionately high and adverse human health effect on any segment of the population. FEMA received a comment on the interim final rule that stated the interim final rule did not overtly discriminate against disaster survivors based on race, color, or national origin, but that it did discriminate covertly against those who are ''financially challenged,'' and, to the extent that the ''financially challenged'' consist disproportionately of minority groups, one might conclude that an element of the IHP program lacks environmental justice. The commenter stated that the housing repair cap of $5,000 has a gross negative impact on low-income disaster survivors, and results in more low-income disaster survivors returning to unsafe, unsanitary, and/or non-functional homes. The commenter recommended the liberal use of housing replacement assistance to provide additional help for the financially challenged.

FEMA addressed this comment in a NPRM that published in the **Federal Register** on July 30, 2012 (*see* 77 FR 44562), and a final rule that published in the **Federal Register** on November 7, 2013 (*see* 78 FR 66852). The $5,000 subcap is no longer in place and individuals and households may receive up to the full amount of IHP funds ($33,000 for fiscal year 2016) for eligible housing repair and replacement assistance. See 80 FR 62086 (Oct. 15, 2015). This figure is adjusted annually to reflect changes in the Consumer Price Index.

No action that FEMA can anticipate under this final rule would have a disproportionately high and adverse human health effect on any segment of the population. In addition, the rulemaking would not impose substantial direct compliance costs on those communities.

K. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

FEMA has analyzed this final rule under Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks, 62 FR 19883, Apr. 23, 1997. This rule is not an economically significant rule and would not create an environmental risk to health or safety that might disproportionately affect children.

L. Executive Order 12988, Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. *See* Executive Order 12988, 61 FR 4729, Feb. 7, 1996.

M. Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights

FEMA has reviewed this rule under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, as supplemented by Executive Order 13406, Protecting the Property Rights of the American People. *See* Executive Order 12630, 53 FR 8859, Mar. 18, 1988, and Executive Order 13406, 71 FR 36973, June 28, 2006. This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630.

N. Congressional Review of Agency Rulemaking

Under the Congressional Review of Agency Rulemaking Act (CRA), 5 U.S.C. 801–808, before a rule can take effect, the Federal agency promulgating the rule must submit to Congress and to the Government Accountability Office (GAO) a copy of the rule, a concise general statement relating to the rule, including whether it is a major rule, the proposed effective date of the rule, a copy of any cost-benefit analysis, descriptions of the agency's actions under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act, and any other information or statements required by relevant executive orders.

FEMA has sent this rule to Congress and to GAO pursuant to the CRA. The rule is not a major rule within the meaning of the CRA. It will not have an annual effect on the economy of $100 million or more, it will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects in 44 CFR Part 206

Administrative practice and procedure, Coastal zone, Community facilities, Disaster assistance, Fire prevention, Grant programs—housing and community development, Housing, Insurance, Intergovernmental relations, Loan programs—housing and

community development, Natural resources, Penalties, and Reporting and recordkeeping requirements.

PART 206—FEDERAL DISASTER ASSISTANCE

■ Accordingly, the amendments to 44 CFR 206.110–120 of the interim final rule published on September 30, 2002 (67 FR 61446), with the corrections published on October 9, 2002 (67 FR 62896), the technical amendments to 206.110, 206.111, 206.112, 206.115, 206.117, and 206.120 published on April 3, 2009 (74 FR 15328), and the amendments to 206.117 published on November 7, 2013 (78 FR 66852), are adopted as a final rule without change.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–24762 Filed 11–14–19; 8:45 am]

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FEDERAL MARITIME COMMISSION

46 CFR Part 515

[Docket No. 18–11]

RIN 3072–AC73

Licensing, Registration, Financial Responsibility Requirements, and General Duties for Ocean Transportation Intermediaries

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Federal Maritime Commission (Commission) amends its rules governing licensing, registration, financial responsibility requirements, and general duties for ocean transportation intermediaries (OTIs). The changes are mainly administrative and procedural.

DATES: The rule is effective December 16, 2019.

FOR FURTHER INFORMATION CONTACT: Sandra L. Kusumoto, Director, Bureau of Certification and Licensing. *Address:* 800 North Capitol Street, NW, Washington, DC 20573–0001. *Phone:* (202) 523–5787. *Email: bcl@fmc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

By Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on December 17, 2018, 83 FR 64502, the Commission proposed changes to 46 CFR part 515, which governs licensing, registration, financial responsibility requirements, and general duties for OTIs. The changes are necessary because while implementing the extensive revisions to part 515 made in a November 5, 2015 final rule (80 FR 68722), the Commission has identified a number of regulatory provisions where clarification is warranted.

The Commission invited comments on the NPRM, and later extended the comment period from January 12, 2019 to February 22, 2019, 84 FR 2125 (February 6, 2019). The Commission received three comments. After consideration of the comments and for the reasons stated below, the Commission is adopting all but one of the proposed amendments to part 515 without change. The exception is the proposed change to § 515.3, which the Commission is deferring while it considers whether this section of its rules will require further revision in light of the recent statutory changes made by the Frank LoBiondo Coast Guard Authorization Act of 2018, Public Law 115–282 (LoBiondo Act).

II. Summary of NPRM

The Commission's proposed changes to its current rules were administrative or procedural in nature or would further reduce the regulatory burden on regulated entities. These proposed changes included: (1) Updating the title and scope of part 515 to include foreign-based non-vessel-operating common carrier (NVOCC) registrations; (2) clarifying the requirements for U.S. agents of foreign-based registered NVOCCs; (3) removing the optional paper application process and related reference to fee amounts; (4) adding language to clarify who can be the Qualifying Individual (QI) in partnerships between entities other than individuals; (5) updating and improving processes (renewal, bond, and termination); (6) adding clarifying language regarding the Commission's direct review of applications in certain cases; (7) clarifying the information that sureties are to provide regarding claims against OTIs; (8) adding a requirement that NVOCCs submit their Form FMC–1 prior to being issued a license; and (9) deleting the reference to the availability of the Regulated Person's Index. None of the proposed changes would increase the burden to applicants, licensees, or foreign-based registered NVOCCs.

III. Summary of Comments

Roanoke Insurance Group Inc. (Roanoke), a provider of surety bonds to OTIs, stated that it endorses and supports the minor administrative modifications the Commission is proposing to part 515. Specifically, Roanoke stated that it believes ''the closer integration between the Tariff and Licensing units during the licensing process, specifically adopting a rule that the [Commission] will not issue the license until the financial responsibility and tariff are in place, is beneficial to the industry.'' Roanoke also had no objection to the proposed clarifications relating to information provided by financial responsibility providers on claims against OTIs.

Distribution-Publications, Inc. (DPI), a tariff publisher, stated in its comments that it agrees ''none of the proposed changes will increase the burden on applicants, licensees or registered foreign-based NVOCCs.'' DPI supports the requirement for NVOCCs to submit the tariff registration form (Form FMC–1) prior to being issued a license and agrees with the Commission that the rule will not add any additional burden to NVOCCs because ''this will merely be a change to the timing of the [tariff publication] requirement.''

The National Customs Brokers and Forwarders Association of America, Inc. (NCBFAA) is a national trade association representing the interests of freight forwarders, NVOCCs, and customs brokers in the ocean shipping industry. The NCBFAA stated that ''the majority of the proposed changes are mainly administrative or procedural and do not raise substantive issues or impose new regulatory obligations on licensees.'' The NCBFAA, however, raised a concern with the proposed changes to § 515.14, namely ''that the duration of an OTI license would be for a period of one to four years, as contrasted with the current three-year initial license period.'' The NCBFAA asserted that ''[a] change of that nature would be both administratively burdensome to the Commission and unnecessarily burdensome to licensees.'' We address this concern below.

IV. Changes to Part 515

Accordingly, the Commission adopts the changes in the proposed rule as follows:

A. Part 515 Title and Scope

The final rule adds ''Registration'' to the part heading to reflect that foreign-based NVOCCs have the option of registering or becoming licensed. The rule also includes registration in the description of the scope of part 515 in § 515.1.

B. U.S. Agents for Registered NVOCCs

The NPRM proposed amending § 515.3 to clarify that licensed OTI agents for foreign-based NVOCCs can be either ocean freight forwarders (OFFs) or NVOCCs. In light of the changes

made by the LoBiondo Act to the licensing requirements in 46 U.S.C. 40901, the Commission is deferring making any changes to § 515.3 while it determines whether the LoBiondo Act requires more substantive revisions to the section. *See* NPRM: Regulatory Amendments Implementing the Frank LoBiondo Coast Guard Authorization Act of 2018, 84 FR 54087 (Oct. 9, 2019).

C. Forms and Application Fees

The final rule removes references in §§ 515.5 and 515.14 to renewal forms for licensed OTIs. These references are not needed because the data collection during the renewal process is the same as the data collection in the initial Form FMC–18.

The final rule also amends §§ 515.5(b) and 515.12(a) to eliminate the paper application option for OTI licenses, based on the Commission's experience since introducing the electronic filing option. The Commission has not received any requests for a waiver to file a paper application since the waiver requirement was implemented in November 2015.

Finally, the final rule replaces an outdated reference to ''Form FMC–18 Rev.'' in §§ 515.5; 515.12 with ''Form FMC–18.''

D. Qualifying Individuals in Partnerships Between Entities

The current qualifying individual (QI) requirements in § 515.11(b) regarding partnerships assume that the managing partners are individuals and thus eligible to be the QI for the partnership. In order to address the situation in which the managing partners are entities rather than individuals, clarifying language has been added indicating that an officer of a general partner entity may be the QI.

E. Submission of Form FMC–1 as Prerequisite for License

The final rule amends § 515.14(a) to require NVOCCs applying for a license to provide the Commission with a Form FMC–1 prior to the Commission issuing a license, which conforms to the current procedures for foreign-based NVOCCs that register with the Commission.[1] Currently, a license is issued after approval by the Commission and receipt of proof of financial responsibility. Although NVOCCs are required under § 520.3 to submit a Form FMC–1 prior to the commencement of common carrier service pursuant to a published tariff, submission of the form is not currently a prerequisite for receiving a license. Like the current requirement for submitting proof of financial responsibility, the final rule requires NVOCCs to submit a Form FMC–1 within 120 days of the conditional approval of their license application. Failure to submit the form within that time period will result in the NVOCC having to submit a new application to restart the license process. This change will ensure that NVOCCs comply with all requirements for commencing service in the U.S. trades in a timely manner. This change will add no additional burden to NVOCCs seeking licenses as they are already required to provide the Commission with a Form FMC–1; the final rule merely affects the timing of the submission of the form.

Because the Form FMC–1 requirements mirror the existing requirements for submitting proof of financial responsibility, the final rule combines the latter requirement from § 515.25 with the Form FMC–1 requirements being added to § 515.14(a).

F. License Renewal Process

The final rule makes a number of changes to § 515.14 to improve and clarify the license renewal process. In addition to some minor clarifying language changes, the final rule changes the initial license period before renewal from three years to a period of not less than one year and not greater than four years. Allowing for a range in the initial period would provide flexibility and account for the varying time periods between submission of an application and issuance of a license due to issues that may arise during the review process or delayed submission of necessary documentation (*e.g.,* proof of financial responsibility).

As noted above, the NCBFAA has concerns about this change, stating that the group assumes that the Commission did not intend for the proposed rule to mean that some licenses would be issued for a period of less than three years, and, instead, that the Commission was trying to ''rationalize the process by which renewal obligations were set.'' The NCBFAA argues that issuing licenses for periods of less than three years would be burdensome for the Commission and licensees and requests that the Commission clarify the proposal.

The NCBFAA is correct that the change to § 515.14(c) is intended to govern how renewal obligations are set. Specifically, the purpose is to enable the Bureau of Certification and Licensing to determine license renewal dates by the license number rather than the initial issuance date of the license in order to evenly distribute license renewals over a 36-month period. An even distribution of license renewals will ensure an effective and efficient renewal process for the increasing OTI licensee population by preventing the potential bunching of license renewals in particular months or years. Such bunching could occur if the initial issuance date of a license was the basis for the renewal, potentially delaying the review and processing of renewals during more populous months or years.

Spreading out the renewal dates, however, necessitates establishing a range of initial license periods for OTIs; otherwise, the initial license period could conflict with the renewal date (*e.g.,* if an OTI had a three-year initial license period but the renewal date was in four years).

Although we understand NCBFAA's concern, the Commission respectfully disagrees with the assertion that this change will be burdensome for the Commission or licensees. As explained above, the purpose of the change is to reduce the burden on the Commission and to provide the industry with efficient and timely renewal processing. Moreover, the change only affects the *initial license period,* which will be one to four years; all subsequent renewal periods will continue to be three years. And although some OTIs will have initial license periods of one to two years, others will have an initial period of three to four years, *i.e.,* longer than the current three-year period. For those OTIs with a shorter initial license period, the Commission expects the renewal burden to be lower than for OTIs with longer initial license periods, given that the shorter duration will decrease the likelihood of any changes needing to be made during the renewal. Overall, the Commission believes that the change will be beneficial to both OTI licensees and the Commission in that it will ensure the timely processing of renewals.

The final rule would also change the deadline for completing the renewal process. Currently, § 515.14 requires licensed OTIs to complete the renewal process no later than 60 days prior to the renewal date. The final rule would change the deadline to the renewal date itself. This change would reduce the burden on licensed OTIs by allowing them additional time to complete the renewal process.

G. Application After Revocation or Denial

The final rule expands the types of applications subject to direct Commission review to include applicants employing the same officers,

[1] The final rule also makes minor clarifying changes to the corresponding requirement in § 515.19 for foreign-based NVOCCs registering with the Commission.

managers, or members of an OTI whose license was revoked or denied within the previous three years and where the Commission determined that the OTI was not qualified to provide OTI services. The applications currently subject to direct Commission review are limited to those submitted by an OTI whose license was previously denied or revoked, or those from another OTI that employs the same QI or is controlled by persons whose conduct formed the basis for the previous revocation or denial. The Commission believes that an OTI employing an officer, manager, or member of another OTI that previously had its license denied or revoked raises the same concerns as an OTI employing the same QI and has concluded that direct review of applications by such OTIs is warranted.

The final rule also adds clarifying language to more clearly reflect that denial of an application under § 515.18 is final and not subject to the hearing procedures in § 515.17.

H. Reporting Changes in Trade Names

The final rule clarifies in § 515.20 that a change in a licensee's name includes adding or deleting a trade name relating to its OTI services. OTIs must seek prior approval from the Commission before making such changes.

I. Proof of Financial Responsibility

The final rule clarifies in § 515.22 that OTIs may submit proof of financial responsibility via email, and, in § 515.26 that the Commission may transmit notices of termination of financial instruments via email. Allowing transmission of this information by email reduces delays and the burdens on both OTIs and the Commission.

The final rule also clarifies that in addition to the principal's name, trade name, and address, the financial responsibility instrument must clearly identify the state of incorporation or formation, and the printed name and title of the signatory.

J. Claims Against an OTI

The final rule clarifies that financial responsibility providers must include a registered foreign-based NVOCC's organization number when notifying the Commission of claims against that NVOCC under § 515.23(c). The current rule requires that financial responsibility providers include an OTI's license number, but registered foreign-based NVOCCs do not have license numbers. This change will ensure that the organization number for registered NVOCCs will be included in claim notifications to the Commission. Notwithstanding the ambiguity in the rule, financial responsibility providers currently provide this information with OTI claim information; thus, this change will not result in any additional burdens for financial responsibility providers.

K. Regulated Persons Index

The final rule deletes § 515.34, which references the availability of the Regulated Persons Index (RPI) on the Commission website. The Commission has determined that because the RPI is available on the website, and the Commission advertises that fact, this section is no longer helpful or necessary.

V. Rulemaking Analyses and Notices

Congressional Review Act

The rule is not a ''major rule'' as defined by the Congressional Review Act, codified at 5 U.S.C. 801 *et seq.* The rule will not result in: (1) An annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies. 5 U.S.C. 804(2).

Regulatory Flexibility Act

The Regulatory Flexibility Act (codified as amended at 5 U.S.C. 601–612) provides that whenever an agency promulgates a final rule after being required to publish a proposed rulemaking under the Administrative Procedure Act (APA) (5 U.S.C. 553), the agency must prepare and make available a final regulatory flexibility analysis (FRFA) describing the impact of the rule on small entities, unless the head of the agency certifies that the rulemaking will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 604–605. Based on the analysis below, the Chairman of the Federal Maritime Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The Commission recognizes that the majority of businesses affected by these rules (OTIs) qualify as small entities under the guidelines of the Small Business Administration. The final rule will not, however, result in a significant economic impact on these businesses. No material changes are being proposed; the proposed rule would make minor changes to the licensing, registration, and financial responsibility processes. Most of the changes will have little to no economic impact on OTIs, while some of the changes, *e.g.,* changes to the deadline for renewing licenses, expressly allowing email transmission of documents between OTIs and the Commission, are expected to reduce burdens on OTIs. Notwithstanding the concerns of the NCBFAA regarding the changes to the initial license period, we conclude that, as discussed above, the change will not meaningfully increase the burden on licensees.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) requires an agency to seek and receive approval from the Office of Management and Budget (OMB) before collecting information from the public. 44 U.S.C. 3507.

The information collection requirements for part 515 are currently authorized under OMB Control Number 3072–0018: *46 CFR 515- Licensing, Financial Responsibility Requirements, and General Duties for Ocean Transportation Intermediaries and Related Forms.* The final rule will result in very minor changes to information collected by the Commission. Specifically, the final rule makes minor adjustments to information provided to the Commission and the timing of such submissions, as well as expressly allowing the submission of certain information by email. No changes are being made, however, to any of the forms in part 515, and none of the changes are expected to affect the burden hours associated with the information collection.

Although the Commission initially concluded in the NPRM that these changes did not warrant revisions to the information collection associated with part 515, the Commission subsequently determined to submit the changes to OMB for approval. Notice of the revised information collection was published in the **Federal Register**; no comments were received. *See* 84 FR 25274 (May 31, 2019) (60-day notice); 84 FR 50036 (Sep. 24, 2019) (30-day notice).

National Environmental Policy Act

The Commission's regulations categorically exclude certain rulemakings from any requirement to prepare an environmental assessment or an environmental impact statement because they do not increase or decrease air, water or noise pollution or the use of fossil fuels, recyclables, or energy. 46 CFR 504.4. This final rule relates to OTI licensing and financial responsibility requirements and therefore falls within the categorical exclusions for matters related to the issuance, modification, denial and revocation of ocean transportation intermediary licenses, and matters related to the receipt of

surety bonds from OTIs. § 504.4(a)(1), (3). Therefore, no environmental assessment or environmental impact statement is required.

Executive Order 12988 (Civil Justice Reform)

This proposed rule meets applicable standards in E.O. 12988 titled, ''Civil Justice Reform,'' to minimize litigation, eliminate ambiguity, and reduce burden.

Regulation Identifier Number

The Commission assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda). The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda, available at *http://www.reginfo.gov/public/do/eAgendaMain*.

List of Subjects in 46 CFR Part 515

Freight, Freight forwarders, Maritime carriers, Reporting and recordkeeping. requirements.

For the reasons stated in the supplementary information, 46 CFR part 515 is amended as follows:

PART 515—LICENSING, REGISTRATION, FINANCIAL RESPONSIBILITY REQUIREMENTS, AND GENERAL DUTIES FOR OCEAN TRANSPORTATION INTERMEDIARIES

■ 1. The authority citation for part 515 continues to read as follows:

Authority: 5 U.S.C. 553; 31 U.S.C. 9701; 46 U.S.C. 305, 40102, 40104, 40501–40503, 40901–40904, 41101–41109, 41301–41302, 41305–41307; Pub. L. 105–383, 112 Stat. 3411; 21 U.S.C. 862.

■ 2. Revise the part heading to read as set forth above.

■ 3. Amend § 515.1 by revising the first sentence of paragraph (a) to read as follows:

§ 515.1 Scope.

(a) This part sets forth regulations providing for the licensing and registration as ocean transportation intermediaries of persons who wish to carry on the business of providing intermediary services, including the grounds and procedures for revocation and suspension of licenses and registrations. * * *

* * * * *

■ 4. Amend § 515.5 by revising paragraphs (a), (b), and (c)(2) to read as follows:

§ 515.5 Forms and fees.

(a) *Forms.* License Application Form FMC–18 is found at the Commission's website *www.fmc.gov* for completion on-line by applicants and licensees. Foreign-based Unlicensed NVOCC Registration/Renewal Form FMC–65 and financial responsibility Forms FMC–48, FMC–67, FMC–68, FMC–69 may be obtained from the Commission's website at *www.fmc.gov,* from the Director, Bureau of Certification and Licensing, Federal Maritime Commission, Washington, DC 20573, or from any of the Commission's Area Representatives.

(b) *Filing of license application forms.* All application forms are to be filed electronically.

(c) * * *

(2) Fees under this part shall be as follows:

(i) Application for new OTI license as required by § 515.12(a): Filing $250.

(ii) Application for change to OTI license or license transfer as required by § 515.20(a) and (b): Filing $125.

■ 5. Amend § 515.11 by revising paragraph (b)(2) to read as follows:

§ 515.11 Basic requirements for licensing; eligibility.

* * * * *

(b) * * *

(2) *Partnership.* At least one of the active managing partners, unless the partners are entities, such as corporations, in which case an officer, member, or manager of one of the entities as long as the entity is a general partner.

* * * * *

■ 6. Amend § 515.12 by revising the first sentence of paragraph (a)(1) to read as follows:

§ 515.12 Application for license.

(a) * * *

(1) Any person who wishes to obtain a license to operate as an ocean transportation intermediary shall submit electronically a completed application Form FMC–18 (Application for a License as an Ocean Transportation Intermediary) in accordance with the automated FMC–18 filing system and corresponding instructions. * * *

* * * * *

■ 7. Amend § 515.14 by revising paragraphs (a), (c), (d)(1), and the first sentence of paragraph (d)(2) to read as follows:

§ 515.14 Issuance, renewal, and use of license.

(a) *Qualification necessary for issuance.* (1) The Commission will issue a license if it determines, as a result of its investigation, that the applicant possesses the necessary experience and character to render ocean transportation intermediary services; has filed the required bond, insurance or other surety; and has electronically submitted Form FMC–1 pursuant to § 520.3 if approved to offer NVOCC service.

(2) If, within 120 days of notification of conditional approval for licensing by the Commission, proof of financial responsibility and, in the case of an NVOCC, the Form FMC–1 is not received, the conditional approval of the application will be invalid. Applicants whose applications/approvals have become invalid may submit a new Form FMC–18, together with the required filing fee, at any time.

* * * * *

(c) *Duration of license.* Licenses shall be issued for an initial period of not less than one year and not greater than four years as determined by the license number and published on the Commission website. Thereafter, licenses will be renewed for sequential three-year periods upon successful completion of the renewal process in paragraph (d) of this section.

(d) * * *

(1) The licensee shall submit the renewal electronically to the Director of the Bureau of Certification and Licensing (BCL) no later than the renewal date as published on the Commission website. The renewal date (month/day) will remain the same for subsequent renewals irrespective of the date on which the license renewal is submitted or when the renewal is accepted by the Commission, unless another renewal date is assigned by the Commission.

(2) Where information identified in an OTI's license renewal process is changed from that set out in its current Form FMC–18 and requires Commission approval pursuant to § 515.20, the licensee must promptly submit a request for such approval on Form FMC–18 together with the required filing fee.

* * *

* * * * *

■ 8. Revise § 515.18 to read as follows:

§ 515.18 Application after revocation or denial.

Whenever a license has been revoked or an application has been denied because the Commission has found the licensee or applicant to be not qualified to render ocean transportation

intermediary services, any further application within 3 years of the Commission's notice of revocation or denial, made by such former licensee or applicant or by another applicant employing the same qualifying individual, officer(s), member(s), manager(s) or controlled by persons on whose conduct the Commission based its determination for revocation or denial, shall be reviewed directly by the Commission. If the Commission denies the application, such denial is final and not subject to the hearing procedures described in §§ 515.15 and 515.17.

■ 9. Amend § 515.19 by revising paragraphs (c), (e), and (g)(1)(viii) to read as follows:

§ 515.19 Registration of foreign-based unlicensed NVOCC.

* * * * *

(c) Registrations are complete upon receipt of a registration form which meets the requirements of this section, evidence of financial responsibility pursuant to § 515.21, and Form FMC–1 pursuant to § 520.3.

* * * * *

(e) A tariff shall not be published and NVOCC service shall not commence until the Commission receives valid proof of financial responsibility from the registrant and a Form FMC–1 has been submitted.

* * * * *

(g) * * *

(1) * * *

(viii) Failure to designate and maintain a person in the United States as legal agent for the receipt of judicial and administrative process, including subpoenas, as required by § 515.24.

* * * * *

■ 10. Amend § 515.20 by revising paragraph (a)(4) to read as follows:

§ 515.20 Changes in organization.

(a) * * *

(4) Any change in a licensee's name, including adding or deleting a trade name relating to its OTI services; or

* * * * *

■ 11. Amend § 515.22 by revising paragraph (e) to read as follows:

§ 515.22 Proof of financial responsibility.

* * * * *

(e) All forms and documents for establishing financial responsibility of ocean transportation intermediaries prescribed in this section shall be submitted to the Director, Bureau of Certification and Licensing, via email to *bcl@fmc.gov*. Such forms and documents must clearly identify the principal's name; trade name, if any; address; the state of incorporation/formation; and the printed name and title of the signatory.

■ 12. Amend § 515.23 by revising paragraph (c)(3) to read as follows:

§ 515.23 Claims against an ocean transportation intermediary.

* * * * *

(c) * * *

(3) Notices required by this section shall include the name of the claimant, name of the court and case number assigned, and the name and license or organization number of the OTI involved. Such notices may include or attach other information relevant to the claim.

* * * * *

■ 13. Amend § 515.25 by revising paragraph (a)(1) to read as follows:

§ 515.25 Filing of proof of financial responsibility.

(a) * * *

(1) *Licenses.* Upon notification by the Commission that an applicant has been conditionally approved for licensing, the applicant shall file with the Director of the Commission's Bureau of Certification and Licensing, proof of financial responsibility in the form and amount prescribed in § 515.21. No license will be issued until the Commission is in receipt of valid proof of financial responsibility.

* * * * *

■ 14. Revise § 515.26 to read as follows:

§ 515.26 Termination of financial responsibility.

No license or registration shall remain in effect unless valid proof of a financial responsibility instrument is maintained on file with the Commission. Upon receipt of notice of termination of such financial responsibility, the Commission shall notify the concerned licensee, registrant, or registrant's legal agent in the United States, by email, mail, courier, or other method reasonably calculated to provide actual notice, at its last known email address or address, that the Commission shall, without hearing or other proceeding, revoke the license or terminate the registration as of the termination date of the financial responsibility instrument, unless the licensee or registrant shall have submitted valid replacement proof of financial responsibility before such termination date. Replacement financial responsibility must bear an effective date no later than the termination date of the expiring financial responsibility instrument.

§ 515.34 [Removed]

■ 15. Remove § 515.34.

By the Commission.

Rachel Dickon,

Secretary.

[FR Doc. 2019–24472 Filed 11–14–19; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF LABOR

48 CFR Part 2902

[DOL Docket No. DOL–2019–0002]

RIN 1291–AA42

Department of Labor Acquisition Regulations: Definitions for Head of Agency, Head of Contracting Activity, and Senior Procurement Executive

AGENCY: Office of the Assistant Secretary for Administration and Management, Department of Labor.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Department of Labor (Department) is confirming the effective date of its direct final rule (DFR) amending three definitions in the Department of Labor Acquisition Regulation (DOLAR). These changes provide the Secretary of Labor with greater flexibility and a streamlined procedure to delegate procurement authority and appoint procurement officials. In the Department's August 29, 2019 DFR, the Department stated that the DFR would become effective on October 28, 2019, if the Department received no significant adverse comments in response to the DFR. The Department did not receive any comments in response.

DATES: This document confirms that the effective date of the DFR published on August 29, 2019 (84 FR 45434) is October 28, 2019. For purposes of judicial review, the Department considers the date of publication of this document as the date of promulgation of the DFR.

FOR FURTHER INFORMATION CONTACT: *Press inquiries:* Ms. Megan P. Sweeney, Office of Public Affairs, Room No. S–2514, U.S. Department of Labor, 200 Constitution Ave, NW, Washington, DC 20210; telephone: (202) 693–4676; email: *sweeney.megan.p@dol.gov.*

General information: Herman J. Narcho, U.S. Department of Labor, Office of the Assistant Secretary for Administration and Management, Office of the Chief Procurement Officer, 200 Constitution Avenue NW, Room N–5305, Washington, DC 20210; telephone (202) 693–7171 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Confirmation of Effective Date

On August 29, 2019, the Department published a DFR amending three DOLAR definitions found at 48 CFR 2902.101(b): Head of Agency, Head of Contracting Activity, and Senior Procurement Executive. The Department stated that it would publish another document confirming the effective date of the DFR if it received no significant adverse comments. The Department received no significant adverse comments. Accordingly, the Department is hereby confirming that the effective date of the DFR published on August 29, 2019, is October 28, 2019.

II. OMB Review Under the Paperwork Reduction Act of 1995

This action does not add or change any information collection requirements subject to OMB approval under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and its implementing regulations at 5 CFR part 1320. The PRA defines a collection of information as the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format. See 44 U.S.C. 3502(3)(A).

In the DFR published on August 29, 2019, the Department provided 30 days for the public to comment on whether approved information collections would be affected by this rulemaking. The agency did not receive any comments on paperwork in response to that notice.

List of Subjects in 48 CFR Part 2902

Government procurement.

Bryan Slater,

Assistant Secretary for Administration and Management, Labor.

[FR Doc. 2019–24682 Filed 11–14–19; 8:45 am]

BILLING CODE 4510–04–P

Proposed Rules

Federal Register
Vol. 84, No. 221
Friday, November 15, 2019

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2017–BT–STD–0003]

Energy Conservation Program: Energy Conservation Standards for Consumer Refrigerators, Refrigerator-Freezers, and Freezers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Request for information.

SUMMARY: The U.S. Department of Energy (''DOE'') is initiating an effort to determine whether to amend the current energy conservation standards for consumer refrigerators, refrigerator-freezers, and freezers. Under the Energy Policy and Conservation Act of 1975, as amended, DOE must review these standards at least once every six years and publish either a notice of proposed rulemaking (''NOPR'') to propose new standards for consumer refrigerators, refrigerator-freezers, and freezers or a notice of determination that the existing standards do not need to be amended. This request for information (''RFI'') solicits information from the public to help DOE determine whether amended standards for consumer refrigerators, refrigerator-freezers, and freezers would result in a significant amount of additional energy savings and whether those standards would be technologically feasible and economically justified. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this RFI).

DATES: Written comments and information are requested and will be accepted on or before December 30, 2019.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2017–BT–STD–0003, by any of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email: ConsumerRefrigFreezer2017STD0003@ee.doe.gov.* Include the docket number EERE–2017–BT–STD–0003 in the subject line of the message.

3. *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section III of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *http://www.regulations.gov/#!docketDetail;D=EERE-2017-BT-TP-0003.* The docket web page contains instructions on how to access all documents, including public comments in the docket. See section III for information on how to submit comments through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

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For further information on how to submit a comment, review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

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I. Introduction

A. Authority and Background

The Energy Policy and Conservation Act of 1975, as amended (''EPCA''),[1] among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B [2] of EPCA established the Energy Conservation

[1] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (Oct. 23, 2018).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

Program for Consumer Products Other Than Automobiles. These products include consumer refrigerators, refrigerator-freezers, and freezers, the subject of this document. (42 U.S.C. 6292(a)(1)) EPCA prescribed energy conservation standards for these products (42 U.S.C. 6295(b)(1)–(2)), and directed DOE to conduct three cycles of rulemakings to determine whether to amend these standards. (42 U.S.C. 6295(b)(3)(A)(i), (b)(3)(B)–(C), and (b)(4))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of Federal preemption in limited instances for particular State laws or regulations, in accordance with the procedures and other provisions set forth under 42 U.S.C. 6297(d).

DOE completed the first of these rulemaking cycles in 1989 and 1990 by adopting amended performance standards for consumer refrigerators, refrigerator-freezers, and freezers manufactured on or after January 1, 1993. 54 FR 47916 (Nov. 17, 1989) (setting amended standards to apply starting on January 1, 1993); 55 FR 42845 (Oct. 24, 1990) (making certain corrections to the 1993 standards). DOE completed a second rulemaking cycle to amend the standards for consumer refrigerators, refrigerator-freezers, and freezers by issuing a final rule in 1997. 62 FR 23102 (Apr. 28, 1997). Most recently, DOE completed a third rulemaking cycle to amend the standards for consumer refrigerators, refrigerator-freezers, and freezers by publishing a final rule in 2011 (''September 2011 Final Rule''). 76 FR 57516 (Sep. 15, 2011). The current energy conservation standards are located in title 10 of the Code of Federal Regulations (''CFR'') part 430, section 32(a). The currently applicable DOE test procedures for consumer refrigerators, refrigerator-freezers, and freezers appear at 10 CFR part 430, subpart B, appendices A and B (''Appendix A'' and ''Appendix B'').

EPCA also requires that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE evaluate the energy conservation standards for each type of covered product, including those at issue here, and publish either a notice of determination that the standards do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1)) EPCA further provides that, not later than 3 years after the issuance of a final determination not to amend standards, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(3)(B)) DOE must make the analysis on which the determination is based publicly available and provide an opportunity for written comment. (42 U.S.C. 6295(m)(2)) In making a determination, DOE must evaluate whether more stringent standards would: (1) Yield a significant savings in energy use and (2) be both technologically feasible and economically justified. (42 U.S.C. 6295(m)(1)(A))

DOE is publishing this RFI to collect data and information to inform its decision consistent with its obligations under EPCA.

B. Rulemaking Process

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products. EPCA requires that any new or amended energy conservation standard be designed to achieve the maximum improvement in energy or water efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) EPCA also precludes DOE from adopting any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) To determine whether a standard is economically justified, EPCA requires that DOE determine whether the benefits of the standard exceed its burdens by considering, to the greatest extent practicable, the following seven factors:

(1) The economic impact of the standard on the manufacturers and consumers of the affected products;

(2) The savings in operating costs throughout the estimated average life of the product compared to any increases in the initial cost, or maintenance expenses;

(3) The total projected amount of energy and water (if applicable) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary of Energy (Secretary) considers relevant. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

DOE fulfills these and other applicable requirements by conducting a series of analyses throughout the rulemaking process. Table I.1 shows the individual analyses that are performed to satisfy each of the requirements within EPCA.

TABLE I.1—EPCA REQUIREMENTS AND CORRESPONDING DOE ANALYSIS

EPCA requirement	Corresponding DOE analysis
Significant Energy Savings	• Shipments Analysis. • National Impact Analysis. • Energy and Water Use Determination.
Technological Feasibility	• Market and Technology Assessment. • Screening Analysis. • Engineering Analysis.
Economic Justification:	
1. Economic impact on manufacturers and consumers	• Manufacturer Impact Analysis. • Life-Cycle Cost and Payback Period Analysis. • Life-Cycle Cost Subgroup Analysis. • Shipments Analysis.

TABLE I.1—EPCA REQUIREMENTS AND CORRESPONDING DOE ANALYSIS—Continued

EPCA requirement	Corresponding DOE analysis
2. Lifetime operating cost savings compared to increased cost for the product.	• Markups for Product Price Determination. • Energy and Water Use Determination. • Life-Cycle Cost and Payback Period Analysis.
3. Total projected energy savings	• Shipments Analysis. • National Impact Analysis.
4. Impact on utility or performance	• Screening Analysis. • Engineering Analysis.
5. Impact of any lessening of competition	• Manufacturer Impact Analysis.
6. Need for national energy and water conservation	• Shipments Analysis. • National Impact Analysis.
7. Other factors the Secretary considers relevant	• Emissions Analysis. • Utility Impact Analysis. • Employment Impact Analysis. • Monetization of Emission Reductions Benefits. • Regulatory Impact Analysis.

As detailed throughout this RFI, DOE is publishing this document seeking input and data from interested parties to aid in the development of the technical analyses on which DOE will ultimately rely to determine whether (and if so, how) to amend the standards for consumer refrigerators, refrigerator-freezers, and freezers.

II. Request for Information and Comments

The following sections identify a variety of issues on which DOE seeks input to aid its development of the technical and economic analyses regarding whether amended energy conservation standards for consumer refrigerators, refrigerator-freezers, and freezers may be warranted. DOE also welcomes comments on other issues relevant to this data-gathering process that may not specifically be identified in this document.

A. Products Covered by This Rulemaking

This RFI covers those products that meet the definitions for refrigerator, refrigerator-freezer, or freezer, as codified in 10 CFR 430.2. The definitions for refrigerators, refrigerator-freezers, and freezers were most recently amended in a test procedure final rule in a separate rulemaking addressing ''miscellaneous refrigeration products'' [3] (MREFs), in which DOE removed reference to food storage, clarified under what conditions the products must be able to maintain compartment temperatures, and excluded products designed to be used without doors, that do not include a compressor and condenser integral to the cabinet assembly, or that would be classified as an MREF. 81 FR 46768 (July 18, 2016).

Specifically, as codified, ''refrigerator'' means a cabinet, used with one or more doors, that has a source of refrigeration that requires single-phase, alternating current electric energy input only and is capable of maintaining compartment temperatures above 32 degrees Fahrenheit (°F) (0 degrees Celsius (°C)) and below 39 °F (3.9 °C). A refrigerator may include a compartment capable of maintaining compartment temperatures below 32 °F (0 °C), but does not provide a separate low temperature compartment capable of maintaining compartment temperatures below 8 °F (− 13.3 °C). A refrigerator does not include: any product that does not include a compressor and condenser unit as an integral part of the cabinet assembly, coolers, or any product that must comply with an applicable miscellaneous refrigeration product energy conservation standard. 10 CFR 430.2.

''Refrigerator-freezer'' means a cabinet, used with one or more doors, that has a source of refrigeration that requires single-phase, alternating current electric energy input only and consists of two or more compartments where at least one of the compartments is capable of maintaining compartment temperatures above 32 °F (0 °C) and below 39 °F (3.9 °C), and at least one other compartment is capable of maintaining compartment temperatures of 8 °F (− 13.3 °C) and may be adjusted by the user to a temperature of 0 °F (− 17.8 °C) or below. A refrigerator-freezer does not include: any product that does not include a compressor and condenser unit as an integral part of the cabinet assembly, or any product that must comply with an applicable miscellaneous refrigeration product energy conservation standard. *Id.*

''Freezer'' means a cabinet, used with one or more doors, that has a source of refrigeration that requires single-phase, alternating current electric energy input only and is capable of maintaining compartment temperatures of 0 °F (− 17.8 °C) or below. A freezer does not include: Any refrigerated cabinet that consists solely of an automatic ice maker and an ice storage bin arranged so that operation of the automatic icemaker fills the bin to its capacity, any product that does not include a compressor and condenser unit as an integral part of the cabinet assembly, or any product that must comply with an applicable miscellaneous refrigeration product energy conservation standard. *Id.*

DOE's regulations at 10 CFR 430.2 also define sub-categories of refrigerators, refrigerator-freezers, and freezers, including compact [4] and built-in [5] product configurations.

[3] ''Miscellaneous refrigeration product'' means a consumer refrigeration product other than a refrigerator, refrigerator-freezer, or freezer, which includes coolers and combination cooler refrigeration products. 10 CFR 430.2. ''Cooler'' means a cabinet, used with one or more doors, that has a source of refrigeration capable of operating on single-phase, alternating current and is capable of maintaining compartment temperatures either no lower than 39 °F (3.9 °C) or in a range that extends no lower than 37 °F (2.8 °C) but at least as high as 60 °F (15.6 °C). *Id.* ''Combination cooler refrigeration product'' means any cooler-refrigerator, cooler-refrigerator-freezer, or cooler-freezer. *Id.*

[4] *Compact refrigerator/refrigerator-freezer/freezer* means any refrigerator, refrigerator-freezer or freezer with a total refrigerated volume of less than 7.75 cubic feet (220 liters). (Total refrigerated volume shall be determined using the applicable test procedure appendix prescribed in 10 CFR part 430 subpart B.) *Id.*

[5] *Built-in refrigerator/refrigerator-freezer/freezer* means any refrigerator, refrigerator-freezer or freezer with 7.75 cubic feet or greater total volume and 24 inches or less depth not including doors, handles, and custom front panels; with sides which are not finished and not designed to be visible after installation; and that is designed, intended, and marketed exclusively (1) To be installed totally encased by cabinetry or panels that are attached during installation, (2) to be securely fastened to adjacent cabinetry, walls or floor, and (3) to either be equipped with an integral factory-finished face or accept a custom front panel. *Id.*

Issue A.1 DOE requests comment on whether the definitions for refrigerator, refrigerator-freezer, and freezer require any revisions—and if so, how those definitions should be revised. DOE also requests feedback on whether the subcategory definitions currently in place are appropriate or whether further modifications are needed. If these subcategory definitions need modifying, DOE seeks specific input on how to define these terms.

Issue A.2 DOE requests comment on whether additional product definitions are necessary to close any potential gaps in coverage between product types. For example, should the definitions be modified to better account for products that maintain compartment temperatures above 0 °F or 8 °F but less than 32 °F (*i.e.,* between the freezer and refrigerator temperature ranges). DOE also seeks input on whether such products currently exist in the market or whether they are being planned for introduction. DOE also requests comment on opportunities to combine product classes that could reduce regulatory burden.

B. Market and Technology Assessment

The market and technology assessment that DOE routinely conducts when analyzing the impacts of a potential new or amended energy conservation standard provides information about the consumer refrigerator, refrigerator-freezer, and freezer industries that will be used in DOE's analysis throughout the rulemaking process. DOE uses qualitative and quantitative information to characterize the structure of the industry and market. DOE identifies manufacturers, estimates market shares and trends, addresses regulatory and non-regulatory initiatives intended to improve energy efficiency or reduce energy consumption, and explores the potential for efficiency improvements in the design and manufacturing of consumer refrigerators, refrigerator-freezers, and freezers. DOE also reviews product literature, industry publications, and company websites. Additionally, DOE considers conducting interviews with manufacturers to improve its assessment of the market and available technologies for consumer refrigerators, refrigerator-freezers, and freezers.

1. Product/Equipment Classes

When evaluating and establishing energy conservation standards, DOE may divide covered products into product classes by the type of energy used, or by capacity or other performance-related features that justify a different standard. (42 U.S.C. 6295(q)) In making a determination whether capacity or another performance-related feature justifies a different standard, DOE must consider such factors as the utility of the feature to the consumer and other factors DOE deems appropriate. *Id.*

For consumer refrigerators, refrigerator-freezers, and freezers, the current energy conservation standards specified in 10 CFR 430.32(a) are based on 42 product classes determined according to the following performance-related features that provide utility to the consumer, in terms of the type and quantity of items that may be stored, method of access to these items, availability of automatically made ice, defrost requirements, and locations where the product may be installed: Type of unit (refrigerator, refrigerator-freezer, or freezer), total refrigerated volume (standard or compact), defrost system (manual, partial automatic, or automatic), presence of through-the-door (''TTD'') ice service, presence of an automatic icemaker, intended installation (*i.e.,* built-in or freestanding), and configuration of compartments and doors. Table II.1 lists the current 42 product classes for consumer refrigerators, refrigerator-freezers, and freezers.

TABLE II.1—CURRENT CONSUMER REFRIGERATOR, REFRIGERATOR-FREEZER, AND FREEZER PRODUCT CLASSES

	Product class
1	Refrigerator-freezers and refrigerators other than all-refrigerators with manual defrost.
1A	All-refrigerators—manual defrost.
2	Refrigerator-freezers—partial automatic defrost.
3	Refrigerator-freezers—automatic defrost with top-mounted freezer without an automatic icemaker.
3–BI	Built-in refrigerator-freezer—automatic defrost with top-mounted freezer without an automatic icemaker.
3I	Refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker without through-the-door ice service.
3I–BI	Built-in refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker without through-the-door ice service.
3A	All-refrigerators—automatic defrost.
3A–BI	Built-in all-refrigerators—automatic defrost.
4	Refrigerator-freezers—automatic defrost with side-mounted freezer without an automatic icemaker.
4–BI	Built-in refrigerator-freezers—automatic defrost with side-mounted freezer without an automatic icemaker.
4I	Refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker without through-the-door ice service.
4I–BI	Built-in refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker without through-the-door ice service.
5	Refrigerator-freezers—automatic defrost with bottom-mounted freezer without an automatic icemaker.
5–BI	Built-in refrigerator-freezers—automatic defrost with bottom-mounted freezer without an automatic icemaker.
5I	Refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker without through-the-door ice service.
5I–BI	Built-in refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker without through-the-door ice service.
5A	Refrigerator-freezer—automatic defrost with bottom-mounted freezer with through-the-door ice service.
5A–BI	Built-in refrigerator-freezer—automatic defrost with bottom-mounted freezer with through-the-door ice service.
6	Refrigerator-freezers—automatic defrost with top-mounted freezer with through-the-door ice service.
7	Refrigerator-freezers—automatic defrost with side-mounted freezer with through-the-door ice service.
7–BI	Built-in refrigerator-freezers—automatic defrost with side-mounted freezer with through-the-door ice service.
8	Upright freezers with manual defrost.
9	Upright freezers with automatic defrost without an automatic icemaker.
9I	Upright freezers with automatic defrost with an automatic icemaker.
9–BI	Built-in upright freezers with automatic defrost without an automatic icemaker.
9I–BI	Built-in upright freezers with automatic defrost with an automatic icemaker.

TABLE II.1—CURRENT CONSUMER REFRIGERATOR, REFRIGERATOR-FREEZER, AND FREEZER PRODUCT CLASSES—Continued

	Product class
10	Chest freezers and all other freezers except compact freezers.
10A	Chest freezers with automatic defrost.
11	Compact refrigerator-freezers and refrigerators other than all-refrigerators with manual defrost.
11A	Compact all-refrigerators—manual defrost.
12	Compact refrigerator-freezers—partial automatic defrost.
13	Compact refrigerator-freezers—automatic defrost with top-mounted freezer.
13I	Compact refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker.
13A	Compact all-refrigerators—automatic defrost.
14	Compact refrigerator-freezers—automatic defrost with side-mounted freezer.
14I	Compact refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker.
15	Compact refrigerator-freezers—automatic defrost with bottom-mounted freezer.
15I	Compact refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker.
16	Compact upright freezers with manual defrost.
17	Compact upright freezers with automatic defrost.
18	Compact chest freezers.

For products with an automatic icemaker, DOE's test procedures specify a constant energy-use adder of 84 kilowatt-hours per year (''kWh/year''), which represents the annual energy consumed by automatic icemakers in consumer refrigerators, refrigerator-freezers, and freezers. With this constant adder, the standard levels for product classes with an automatic icemaker are equal to the standards of their counterparts without an icemaker plus the 84 kWh/year. Because the standards for the product classes with and without automatic icemakers are effectively the same, except for the constant adder, there may be an opportunity to merge product classes to limit the total number of overall product classes for consumer refrigerators, refrigerator-freezers, and freezers. The energy consumption associated with automatic icemaking could then be incorporated into product labeling rather than the energy conservation standard.

In the most recent energy conservation standards rulemaking for consumer refrigerators, refrigerator-freezers, and freezers, DOE considered combining certain product classes that include products with similar features and operation. Specifically, DOE sought feedback on combining product classes 1 and 2, and product classes 11 and 12. 75 FR 59470, 59493–59494 (Sep. 27, 2010). DOE received mixed feedback on this issue, with comments responding to the NOPR for that rulemaking generally favoring the continued separation of these product classes. As a result, DOE did not merge these product classes in the 2011 Final Rule. 76 FR 57516, 57536 (Sept. 15, 2011).

Issue B.1 DOE requests feedback on the current consumer refrigerator, refrigerator-freezer, and freezer product classes and whether changes to these individual product classes and their descriptions should be made or whether certain classes should be merged or separated (*e.g.,* combining separate product classes equipped with and without automatic icemakers or combining certain classes, such as product classes 1 and 2, or product classes 11 and 12). DOE further requests feedback on whether combining certain classes could impact product utility by eliminating any performance-related features or impact the stringency of the current energy conservation standard for these products. DOE also requests comment on separating any of the existing product classes and whether it would impact product utility by eliminating any performance-related features or reduce any compliance burdens.

DOE is also aware that new configurations and features are available for consumer refrigerators, refrigerator-freezers, and freezers that may not have been available at the time of the last energy conservation standards analysis. Products with multiple compartments, some of which may be intended for storing certain types of food or beverages rather than general fresh food and freezer compartments, may have different energy performance compared to typical product setups. Additionally, product features such as accessible door storage and connected functions may affect product performance compared to those without such features.

Issue B.2 DOE seeks information regarding any other new product classes it should consider for inclusion in its analysis. Specifically, DOE requests information on the performance-related features (*e.g.,* connected functionality, door-in-door designs, display screens, *etc.*) that provide unique consumer utility and data detailing the corresponding impacts on energy use that would justify separate product classes (*i.e.,* explanation for why the presence of these performance-related features would increase energy consumption).

2. Technology Assessment

In analyzing the feasibility of potential new or amended energy conservation standards, DOE uses information about existing and past technology options and prototype designs to help identify technologies that manufacturers could use to meet and/or exceed a given set of energy conservation standards under consideration. In consultation with interested parties, DOE intends to develop a list of technologies to consider in its analysis. That analysis will likely include a number of the technology options DOE previously considered during its most recent rulemaking for consumer refrigerators, refrigerator-freezers, and freezers. A complete list of those prior options appears in Table II.2. As certain technologies have progressed since the 2011 Final Rule, Table II.3 lists newer technology options that DOE may also consider in a future consumer refrigerator, refrigerator-freezer, and freezer rulemaking.

TABLE II.2—PREVIOUSLY CONSIDERED TECHNOLOGY OPTIONS FOR CONSUMER REFRIGERATORS, REFRIGERATOR-FREEZERS, AND FREEZERS FROM THE 2011 FINAL RULE

Insulation:	Fans and Fan Motor:
Improved resistivity of insulation	Evaporator fan and fan motor improvements
Increased insulation thickness	Condenser fan and fan motor improvements
Vacuum-insulated panels (VIPs)	Expansion Valve:
Gas-filled panels	Improved expansion valves
Gasket and Door Design:	Cycling Losses:
Improved gaskets	Fluid control or solenoid valve
Double door gaskets	Defrost System:
Improved door face frame	Reduced energy for automatic defrost
Reduced heat load for TTD feature	Adaptive defrost
Anti-Sweat Heater:	Condenser hot gas
Condenser hot gas	Control System:
Electric heater sizing	Temperature control
Electric heater controls	Air-distribution control
Compressor:	Other Technologies:
Improved compressor efficiency	Alternative refrigerants
Variable-speed compressors	Component location
Linear compressors	Alternative Refrigeration Cycles/Systems:
Evaporator:	Lorenz-Meutzner cycle
Increased surface area	Dual-loop system
Improved heat exchange	Two-stage system
Condenser:	Control valve system
Increased surface area	Ejector refrigerator
Improved heat exchange	Tandem system
Forced-convection condenser	Stirling cycle *
	Thermoelectric *
	Thermoacoustic *

* DOE's definitions for refrigerators, refrigerator-freezers, and freezers exclude products that do not include compressor and condenser units as an integral part of the cabinet assembly. 10 CFR 430.2. Therefore, because these options do not meet this requirement, DOE is not seeking information on these refrigeration technologies as part of this RFI.

TABLE II.3—NEW TECHNOLOGY OPTIONS FOR CONSUMER REFRIGERATORS, REFRIGERATOR-FREEZERS, AND FREEZERS

Insulation:	Evaporator:
Improved VIPs	Sequential dual evaporator
Improved blowing agents	Condenser:
Compressor:	Heat-storage condenser with phase change materials
Large compressors with phase change material	Condensers with microchannel heat exchangers
Solid state thermal cooling technology	Other Technologies:.
Inert blowing fluid CO_2	Alternative refrigerants—*e.g.,* propane, isobutane
	Door-in-door design

Issue B.3 DOE seeks information on the technologies listed in Table II.2 regarding their applicability to the current market and how these technologies may impact the efficiency of consumer refrigerators, refrigerator-freezers, and freezers as measured according to the DOE test procedure. DOE also seeks information on how these technologies may have changed since they were considered in the 2011 Final Rule analysis. Specifically, DOE seeks information on the range of efficiencies or performance characteristics that are currently available for each technology option.

Issue B.4 DOE seeks information on the technologies listed in Table II.3 regarding their market adoption, costs, and any concerns with incorporating them into products (*e.g.,* impacts on consumer utility, potential safety concerns, manufacturing/production/implementation issues, *etc.*).

Issue B.5 DOE seeks information on the availability of improved insulation for consumer refrigerators, refrigerator-freezers, and freezers, specifically on the use of polyurethane (''PU'') foam and VIPs. At the time of the 2011 Final Rule, vendors indicated that there was ongoing work with PU foam insulation that may lead to improvements in insulation performance. DOE seeks any information on the current and projected future status of improved PU foam insulation as a viable design option for the products at issue, and whether improved PU foam insulation has entered the market. During the 2011 Final Rule analysis, DOE noted that manufacturers had varying levels of success implementing VIPs into their products. DOE also seeks information on what advances, if any, the insulation and consumer refrigerator, refrigerator-freezer, and freezer industries have made with respect to the incorporation of VIP technologies.

Issue B.6 DOE seeks comment on other technology options that it should consider for inclusion in its analysis and if these technologies may impact product features or consumer utility.

In October 2016, the 28th Meeting of the Parties to the Montreal Protocol adopted the Kigali Amendment to reduce consumption and production of hydrofluorocarbons (''HFCs''). The Kigali Amendment entered into force on January 1, 2019, for those parties who have ratified the Amendment by that time.[6] On December 1, 2016, the Environmental Protection Agency (''EPA'') published a final rule in the **Federal Register** under its Significant New Alternatives Policy (''SNAP'') program that, amongst other things, changed the status from acceptable to unacceptable of certain HFC-based refrigerants (*e.g.,* R–134a) commonly

[6] *https://ozone.unep.org/sites/default/files/2019-07/MP_Handbook_2019.pdf.*

used in consumer refrigerators, refrigerator-freezers, and freezers as of January 1, 2021. 81 FR 86778. The validity of that approach, however, has been the subject of a legal challenge regarding EPA's use of its SNAP authority to require manufacturers to replace HFCs with a substitute substance and the December 2016 SNAP rule was partially vacated by the court.[7] On August 8, 2018, the EPA published a separate final rule under its SNAP program that modified the use conditions for three flammable refrigerants used in household refrigerators, freezers, and combination refrigerators and freezers. 83 FR 38969. This rule, among other modifications, increased the allowable charge limits for propane and isobutane when used in consumer refrigeration products.

DOE understands that, while the United States has not yet ratified the Kigali Amendment, a significant portion of refrigerators, refrigerator-freezers, and freezers currently use HFC-based refrigerants and may become affected by this Amendment to the Montreal Protocol. DOE plans to account for the impacts, if any, from this Amendment and the SNAP regulations on the consumer refrigerator, refrigerator-freezer, and freezer markets addressed by this RFI in each of the analytical cases that DOE routinely examines, including the no-new-standards analytical case (*i.e.,* without an amended energy conservation standard).

Issue B.7 DOE seeks information related to alternative HFC-free refrigerants, including propane and isobutane. Specifically, DOE seeks information on the availability of such refrigerants and their applicability and/or penetration in the current market (including whether charge limits or safety standards (for example, Underwriter's Laboratory's (''UL'') Standard 60335–2–24, ''Safety Requirements for Household and Similar Electrical Appliances, Part 2: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers'' (2nd Edition, April 28, 2017)) would restrict their use). DOE also requests information on which alternative refrigerant is the most appropriate substitute for R–134a and why.

Issue B.8 DOE requests information and data on the fractional change in efficiency and cost associated with converting an HFC-based refrigerator, refrigerator-freezer, or freezer to an HFC-free refrigerator, refrigerator-freezer, or freezer (both per-unit costs and conversion costs). DOE also seeks feedback on whether the conversion to HFC-free refrigeration systems would affect the availability of any product features (*e.g.,* volumes, configurations, *etc.*) Additionally, if the use of HFC refrigerants were to remain an available option to manufacturers, would this factor impact the efficiency and related costs of these products relative to products that rely on HFC-free refrigerants? If so, how? What would the extent of these efficiency and cost impacts be?

Issue B.9 DOE also requests data on the current and historical (past five years) fraction of HFC-free sales by product type (*e.g.,* top-mount, side-mount, and bottom-mount refrigerator-freezers, or upright and chest freezers).

C. Screening Analysis

The purpose of the screening analysis is to evaluate the technologies that improve equipment efficiency to determine which technologies will be eliminated from further consideration and which will be passed to the engineering analysis for further consideration.

DOE determines whether to eliminate certain technology options from further consideration based on the following criteria:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production of a technology in commercial products and reliable installation and servicing of the technology could not be achieved on the scale necessary to serve the relevant market at the time of the effective date of the standard, then that technology will not be considered further.

(3) *Impacts on equipment utility or equipment availability.* If a technology is determined to have significant adverse impact on the utility of the equipment to significant subgroups of consumers, or result in the unavailability of any covered equipment type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as equipment generally available in the United States at the time, it will not be considered further.[8]

(4) *Adverse impacts on health or safety.* If it is determined that a technology will have significant adverse impacts on health or safety, it will not be considered further.

10 CFR part 430, subpart C, appendix A, 4(a)(4) and 5(b).

Technology options identified in the technology assessment are evaluated against these criteria using DOE analyses and inputs from interested parties (*e.g.,* manufacturers, trade organizations, and energy efficiency advocates). Technologies that pass through the screening analysis are referred to as ''design options'' in the engineering analysis. Technology options that fail to meet one or more of the four criteria are eliminated from consideration.

Table II.4 summarizes the screened out technology options, and the applicable screening criteria, from the 2011 Final Rule.

[6] *https://ozone.unep.org/sites/default/files/2019-07/MP_Handbook_2019.pdf.*

[7] In August 2017, the U.S. Court of Appeals for the District of Columbia Circuit vacated and remanded a July 2015 EPA final rule (80 FR 42870 (July 20, 2015)) to the extent that it required manufacturers to replace HFCs with a substitute substance. *See Mexichem Fluor, Inc.* v. *EPA,* 866 F.3d 451 (D.C. Cir. 2017); *cert. denied* 139 S.Ct. 322 (Oct. 9, 2018). Subsequent to the decision in the *Mexichem* case, the court vacated the December 2016 EPA final rule to the extent it requires manufacturers to replace HFCs that were previously and lawfully installed as substitutes for ozone-depleting substances. Case No. 17–1024 (D.C. Cir. April 5, 2019). DOE will consider the potential impact, if any, of the court's decisions and remand on the products addressed by this RFI.

TABLE II.4—PREVIOUSLY SCREENED OUT TECHNOLOGY OPTIONS FROM THE 2011 FINAL RULE

Screened technology option	EPCA Criteria (X = basis for screening out)			
	Technological feasibility	Practicability to manufacture, install, and service	Adverse impact on product utility	Adverse impacts on health and safety
Improved PU Insulation Resistivity	X			
Gas-Filled Panels	X	X		
Improved Gaskets, Double Gaskets, Improved Door Frame		X	X	
Linear Compressors	X			
Improved Heat Exchange	X		X	
Component Location		X	X	X
Lorenz-Meutzner Cycle	X	X		
Two-Stage System	X	X		
Control Valve System and Tandem System	X	X		
Ejector Refrigerator	X	X		
Stirling Cycle *	X	X		
Thermoelectric*	X	X		
Thermoacoustic *	X	X		

* As stated in the note to Table II.2, DOE's definitions for refrigerator, refrigerator-freezer, and freezer exclude products without compressor and condenser units as an integral part of the cabinet assembly, so DOE would not consider these technology options in a future energy conservation standards rulemaking.

Issue C.1 DOE requests feedback on what impact, if any, the four screening criteria described in this section would have on each of the technology options listed in Table II.2 and Table II.3 with respect to consumer refrigerators, refrigerator-freezers, and freezers. Similarly, DOE seeks information regarding how these same criteria would affect any other technology options not already identified in this document with respect to their potential use in refrigerators, refrigerator-freezers, and freezers.

Issue C.2 With respect to the screened out technology options listed in Table II.4, DOE seeks information on whether these options would, based on current and projected assessments regarding each of them, remain screened out under the four screening criteria described in this section. With respect to each of these technology options, what steps, if any, could be (or have already been) taken to facilitate the introduction of each option as a means to improve the energy performance of consumer refrigerators, refrigerator-freezers, and freezers and the potential to impact consumer utility of the refrigerators, refrigerator-freezers, and freezers.

D. Engineering Analysis

The engineering analysis estimates the cost-efficiency relationship of products at different levels of increased energy efficiency (''efficiency levels''). This relationship serves as the basis for the cost-benefit calculations for consumers, manufacturers, and the Nation. In determining the cost-efficiency relationship, DOE estimates the increase in manufacturer production cost (''MPC'') associated with increasing the efficiency of products above the baseline, up to the maximum technologically feasible (''max-tech'') efficiency level for each product class.

DOE historically has used the following three methodologies to generate incremental manufacturing costs and establish efficiency levels (''ELs'') for analysis: (1) The design-option approach, which provides the incremental costs of adding to a baseline model design options that will improve its efficiency; (2) the efficiency-level approach, which provides the relative costs of achieving increases in energy efficiency levels, without regard to the particular design options used to achieve such increases; and (3) the cost-assessment (or reverse engineering) approach, which provides ''bottom-up'' manufacturing cost assessments for achieving various levels of increased efficiency, based on detailed data as to costs for parts and material, labor, shipping/packaging, and investment for models that operate at particular efficiency levels.

1. Baseline Efficiency Levels

For each established product class, DOE selects a baseline model as a reference point against which any changes resulting from energy conservation standards can be measured. The baseline model in each product class represents the characteristics of common or typical products in that class. Typically, a baseline model is one that meets the current minimum energy conservation standards and provides basic consumer utility.

If it determines that a rulemaking is necessary, consistent with this analytical approach, DOE tentatively plans to consider the current minimum energy conservations standards (which went into effect September 15, 2014) to establish the baseline efficiency levels for each product class. The current standards for each product class are based on the maximum allowable annual energy use in kWh/year and determined according to an equation using the product's calculated adjusted volume (''AV'') in cubic feet (''ft^3''). The current standards for consumer refrigerators, refrigerator-freezers, and freezers are found in 10 CFR 430.32(a).

Issue D.1 DOE requests feedback on whether using the current established energy conservation standards for consumer refrigerators, refrigerator-freezers, and freezers are appropriate baseline efficiency levels for DOE to apply to each product class in evaluating whether to amend the current energy conservation standards for these products. DOE requests data and suggestions to evaluate the baseline efficiency levels in order to better evaluate amending energy conservation standards for these products.

Issue D.2 DOE requests feedback on the appropriate baseline efficiency levels for any newly analyzed product classes that are not currently in place or for the contemplated combined product classes, as discussed in section II.B.1 of this document. For newly analyzed product classes, DOE requests energy use data to develop a baseline

relationship between energy use and adjusted volume.

2. Maximum Available and Maximum Technology Levels

As part of DOE's analysis, the maximum available efficiency level is the highest efficiency unit currently available on the market. For the 2011 Final Rule, DOE did not analyze all 42 consumer refrigerator, refrigerator-freezer, and freezer product classes. Rather, DOE focused on 11 product classes. Seven of the 11 analyzed product classes represented over 90 percent of product shipments in the market at the time of the analysis. *See* 76 FR 57516, 57530 and chapter 2 of the preliminary analysis technical support document (''TSD'') for that rulemaking. The current maximum available efficiencies for these 11 analyzed product classes are included in Table II.5.

TABLE II.5—MAXIMUM EFFICIENCY LEVELS CURRENTLY AVAILABLE

Product class	Rated energy use percentage below maximum allowable limit	Adjusted volume (ft^3)
3	14	17
5	32	13
7	28	32
9	25	24
10	17	18
11	22	3
18	26	12
3A–BI	37	12
5–BI	17	11
7–BI	9	32, 33, 37
9I–BI	25	28

Source: DOE Compliance Certification Database (as of April 9, 2019).

DOE defines a max-tech efficiency level to represent the theoretical maximum possible efficiency if all available design options are incorporated in a product. In many cases, the max-tech efficiency level is not commercially available because it is not economically feasible. In the 2011 Final Rule, DOE determined max-tech efficiency levels using energy modeling. These energy models were based on use of all design options applicable to the specific product classes. While these product configurations had not likely been tested as prototypes, all of the individual design options had been incorporated in available products.

Issue D.3 DOE seeks input and data that would allow it to evaluate the appropriateness and technological feasibility of the maximum available efficiency levels for potential consideration as possible energy conservation standards for the products at issue. DOE also requests feedback on whether the maximum available efficiencies presented in Table II.5 are representative of those for the other consumer refrigerator, refrigerator-freezer, and freezer product classes not directly analyzed in the 2011 Final Rule. If the range of possible efficiencies is different for the other product classes not directly analyzed, DOE requests alternative approaches that should be considered for those product classes and data and information to support use of the alternative.

Issue D.4 DOE seeks feedback on what design options would be incorporated at a max-tech efficiency level, and the efficiencies associated with those levels. As part of this request, DOE also seeks information as to whether there are limitations on the use of certain combinations of design options.

3. Manufacturer Production Costs and Manufacturing Selling Price

As described at the beginning of this section, the main outputs of the engineering analysis are cost-efficiency relationships that describe the estimated increases in manufacturer production cost associated with higher-efficiency products for the analyzed product classes. For the 2011 Final Rule, DOE developed the cost-efficiency relationships by estimating the efficiency improvements and costs associated with incorporating specific design options into the assumed baseline model for each analyzed product class.

Issue D.5 DOE requests feedback on how manufacturers would incorporate the technology options listed in Table II.2 and Table II.3 to increase energy efficiency in consumer refrigerators, refrigerator-freezers, and freezers beyond the baseline. This includes information on the order in which manufacturers would incorporate the different technologies to incrementally improve the efficiencies of products. DOE also requests feedback on whether the increased energy efficiency would lead to other design changes that would not occur otherwise. DOE is also interested in information regarding any potential impact of design options on a manufacturer's ability to incorporate additional functions or attributes in response to consumer demand.

Issue D.6 DOE also seeks input on the increase in MPC associated with incorporating each particular design option. Specifically, DOE is interested in whether and how the costs estimated for design options in the 2011 Final Rule have changed since the time of that analysis. DOE also requests information on the investments necessary to incorporate specific design options, including, but not limited to, costs related to new or modified tooling (if any), materials, engineering and development efforts to implement each design option, and manufacturing/production impacts.

Issue D.7 DOE requests comment on whether certain design options may not be applicable to (or are incompatible with) specific product classes.

As described in section II.D.2 of this document, DOE analyzed 11 product classes in the 2011 Final Rule. DOE developed cost-efficiency curves for each of these product classes that were used as the input for the downstream analyses conducted in support of that rulemaking. See chapter 5 of the 2011 Final Rule TSD for the cost-efficiency curves developed in that rulemaking.

Issue D.8 DOE seeks feedback on whether the approach of analyzing a sub-set of product classes is appropriate for a future consumer refrigerator, refrigerator-freezer, and freezer energy conservation standards rulemaking. DOE requests comment on whether it is necessary to individually analyze all 11 product classes used in the 2011 Final Rule. For example, analysis on the built-in product classes may not be necessary if the analysis on the corresponding freestanding product classes is applicable to both product classes. Additionally, DOE requests data and suggestions to evaluate the approach used to apply the analyzed product class results to other product classes. For example, if it is necessary to individually analyze more than 11 product classes used in the 2011 Final Rule, DOE requests information on why aggregating certain products is not appropriate. If this approach is not appropriate, DOE requests alternative approaches and data and information that would support the use of the alternative.[9]

To account for manufacturers' non-production costs and profit margin, DOE applies a non-production cost multiplier (the manufacturer markup) to the MPC. The resulting manufacturer selling price (''MSP'') is the price at which the manufacturer distributes a unit into commerce. For the 2011 Final Rule, DOE used a manufacturer markup of 1.26 for all non-built-in products and a manufacturer markup of 1.40 for built-in products. See chapter 6 of the 2011 Final Rule TSD.

Issue D.9 DOE requests feedback on whether manufacturer markups of 1.26 and 1.40 are appropriate for non-built-in and built-in products, respectively.

E. Distribution Channels

In generating end-user price inputs for the life-cycle cost (''LCC'') analysis and national impact analysis (''NIA''), DOE must identify distribution channels (*i.e.,* how the products are distributed from the manufacturer to the consumer), and estimate relative sales volumes through each channel. In the 2011 Final Rule, DOE only accounted for the retail outlets distribution channel because data from the Association of Home Appliance Manufacturers (''AHAM'') 2005 *Fact Book* indicates that the overwhelming majority of residential appliances were sold through retail outlets. In that rulemaking, DOE did not include a separate distribution channel for refrigeration products included as part of a new home because DOE did not have enough information to characterize which of these products were ''pre-installed'' by builders in these new homes. Should sufficient information become available, DOE may consider including a separate distribution channel that includes a contractor in addition to the existing retail outlets distribution channel.

Issue E.1 DOE requests information on the existence of any distribution channels other than the retail outlet distribution channel that are used to distribute the products at issue into the market. DOE also requests data on the fraction of full-size consumer refrigerator and refrigerator-freezer sales in the residential sector that go through both a wholesaler/retailer and a contractor as well as the fraction of sales that go through any other identified channels.

F. Energy Use Analysis

As part of the rulemaking process, DOE conducts an energy use analysis to identify how products are used by consumers, and thereby determine the energy savings potential of energy efficiency improvements. DOE bases the energy consumption of consumer refrigerators, refrigerator-freezers, and freezers on the rated annual energy consumption as determined by the DOE test procedure. Along similar lines, the energy use analysis is meant to represent typical energy consumption in the field.

1. Usage Adjustment Factor

In the 2011 Final Rule, DOE incorporated a usage adjustment factor (''UAF''), which served to correct for differences in a product's actual energy use in the field and the product's energy use as determined by the DOE test procedure. Average UAFs were calculated for each product class, and most product classes incorporated an age-dependent UAF, and a distribution of UAFs dependent on the average outdoor temperature, as well as the number of occupants across the household sample in the LCC; additionally, separate UAFs were calculated for primary and secondary refrigerators. Since the publication of the 2011 Final Rule, DOE amended its test procedure for these products. 79 FR 22320 (April 21, 2014).

Issue F.1 DOE requests feedback and data on whether a product's energy use results from the current test procedure accurately reflect the product's average energy use in the field, thereby rendering an average UAF unnecessary for this rulemaking. If the UAF is still necessary, DOE requests data and information to allow it to better evaluate the representativeness of the current UAF. DOE also requests suggestions and data that would allow DOE to evaluate steps that could be taken to bring these two values into closer harmony.

Issue F.2 DOE also requests feedback and data on how a product's energy use changes with age, how the number of occupants in the household affects the product's energy use, and whether separate UAFs for primary and secondary refrigerator-freezers are necessary.

2. Connected Refrigerators, Refrigerator-Freezers, and Freezers

DOE is aware of the introduction of internet-connected refrigerators and refrigerator-freezers on the market. DOE recently published an RFI on the emerging smart technology appliance and equipment market. 83 FR 46886 (Sept. 17, 2018). In that RFI, DOE sought information to better understand market trends and issues in the emerging market for appliances and commercial equipment that incorporate smart technology. DOE's intent in issuing the RFI was to ensure that DOE did not inadvertently impede such innovation in fulfilling its statutory obligations in setting efficiency standards for covered products and equipment. Additionally, as discussed in the RFI, DOE lacks data regarding consumer use of connected features.

Issue F.3 DOE requests information and data specific to consumer use and the associated power consumption of connected features on internet-connected refrigerators, refrigerator-freezers, and freezers.

G. Repair and Maintenance Costs

In the 2011 Final Rule, DOE estimated the increase in repair costs from using specific technology found in some higher efficiency design options; however, DOE excluded maintenance costs from its analysis because there was no evidence that maintenance costs change by efficiency level. In the 2011 Final Rule analysis, DOE used relative component repair rates from a prior rulemaking for commercial refrigeration equipment combined with aggregate survey data from Consumers Union collected in 2009 to estimate the repair rate by product class and efficiency level. To estimate the repair costs, DOE used incremental cost models developed in the engineering analysis in addition to baseline repair cost data from Best Buy Co., Inc.

Issue G.1 DOE requests feedback and data on whether maintenance costs differ in comparison to the baseline

[9] See chapter 2, section 2.15 in the preliminary analysis TSD published during the rulemaking process leading to the 2011 Final Rule, document #22 on *regulations.gov* in docket ID EERE–2008–BT–STD–0012.

maintenance costs for any of the specific technology options listed in Table II.2 and Table II.3. To the extent that these costs differ, DOE seeks supporting data and the reasons for those differences.

Issue G.2 DOE requests information and data on the frequency of repair and repair costs by product class for the technology options listed in Table II.2 and Table II.3. While DOE is interested in information regarding each of the listed technology options, DOE is particularly interested in the impacts on repair frequencies and costs with respect to those products that use VIPs and variable-speed compressors. DOE is also interested in whether consumers simply replace the products when they fail as opposed to repairing them.

H. Shipments

DOE develops shipments forecasts of consumer refrigerators, refrigerator-freezers, and freezers to calculate the national impacts of potential amended energy conservation standards on energy consumption, net present value (''NPV''), and future manufacturer cash flows. DOE shipments projections are based on available historical data broken out by product class, capacity, and efficiency. Current sales estimates allow for a more accurate model that captures recent trends in the market.

Issue H.1 DOE requests 2018 annual sales data (*i.e.,* number of shipments) for refrigerators with a top-mounted freezer, TTD refrigerators with a bottom-mounted freezer, non-TTD refrigerators with a bottom-mounted freezer, refrigerators with a side-mounted freezer, compact refrigerators, chest freezers, and upright freezers. For each category, DOE also requests the fraction of sales that are ENERGY STAR-qualified.

Issue H.2 DOE requests 2018 data on the fraction of sales in the residential and commercial sector for full-size refrigerators, compact refrigerators, and freezers.

Issue H.3 DOE requests 2018 data on the fraction of sales of full-size refrigerators, compact refrigerators, and upright freezers that are built-in models.

If disaggregated fractions of annual sales are not available at the product type level, DOE requests more aggregated fractions of annual sales at the category level.

Issue H.4 If available, DOE requests the same information for the previous five years (2013–2017).

Issue H.5 DOE requests available 2018 sales data on the fraction of full-size refrigerator sales by technology for the technology options listed in Table II.2 and Table II.3, and in particular, for VIPs and variable-speed compressors. DOE also requests information on any expected market trends in the popularity of those technology options.

Issue H.6 DOE requests data and information on any trends in the refrigeration market that could be used to forecast expected trends in product class market share, as well as market share of efficiency levels within each product class. DOE also requests data and information on the existence of price learning for refrigeration products, which could impact market shares over the analysis period.

Issue H.7 DOE has identified several new features, such as door-in-door configuration and ''smart'' internet-connected refrigerators, which may impact total energy consumption. DOE requests input on any expected market trends for such features.

Issue H.8 An initial analysis of data from the Residential Energy Consumption Surveys (''RECSs'') from 1993–2015 indicates that consumers are purchasing higher-capacity refrigerators over time. For example, estimates show that purchases of refrigerators greater than or equal to 22.6 cubic feet rose from 10 percent to 50 percent of the market from 2000 to 2015. In the same time period, sales of refrigerators less than 17.6 cubic feet decreased from 43 percent to 6 percent of the market. DOE seeks data and information on whether the trend towards increased sales of higher-capacity units has continued through 2018 or has leveled off. If the trend has continued, DOE requests data on which capacities have seen significant changes from 2009 to 2018 and by how much. DOE requests input on expected capacity market trends over the next 5 years. Additionally, DOE requests feedback on the drivers of this market shift towards larger-capacity refrigerators.

Issue H.9 In the 2011 Final Rule, DOE developed a lifetime model for standard-size refrigerator-freezers, standard-size freezers, and compact refrigeration products. In addition, DOE derived a conversion function to model the conversion from primary to secondary refrigerator-freezers. The mean lifetimes were 17.4 years, 22.3 years, 5.6 years, and 7.5 years for standard-size refrigerator-freezers, standard-size freezers, compact refrigerators, and compact freezers, respectively. The primary-to-secondary conversion model indicated that 5.6 percent of standard-size refrigerator-freezer shipments are sold as new secondary units and that roughly 1.5 percent of surviving refrigerator-freezers are converted from primary to secondary each year. Because the conversion and lifetime models affect the shipments analysis (as well as the LCC and payback period (''PBP'') analyses), DOE requests data and information to inform the average lifetime of refrigeration products and the conversion of primary to secondary refrigerator-freezers.

I. Manufacturer Impact Analysis

The purpose of the manufacturer impact analysis (''MIA'') is to estimate the financial impact of amended energy conservation standards on manufacturers of consumer refrigerators, refrigerator-freezers, and freezers, and to evaluate the potential impact of such standards on direct employment and manufacturing capacity. The MIA includes both quantitative and qualitative aspects. The quantitative part of the MIA primarily relies on the Government Regulatory Impact Model (''GRIM''), an industry cash-flow model adapted for each product in this rulemaking, with the key output of industry net present value (''INPV''). The qualitative part of the MIA addresses the potential impacts of energy conservation standards on manufacturing capacity and industry competition, as well as factors such as product characteristics, impacts on particular subgroups of firms, and important market and product trends.

As part of the MIA, DOE intends to analyze impacts of amended energy conservation standards on subgroups of manufacturers of covered products, such as small business manufacturers. DOE intends to use the Small Business Administration's (''SBA'') small business size standards to determine whether manufacturers qualify as small businesses, which are listed by the applicable North American Industry Classification System (''NAICS'') code.[10] Manufacturing of consumer refrigerators, refrigerator-freezers, and freezers is classified under NAICS 335220, ''Major Household Appliance Manufacturing,'' and the SBA sets a threshold of 1,500 employees or less for a domestic entity to be considered as a small business. This employee threshold includes all employees in a business' parent company and any other subsidiaries.

One aspect of assessing manufacturer burden involves looking at the cumulative impact of multiple DOE standards and the product-specific regulatory actions of other Federal agencies that affect the manufacturers of a covered product or equipment. While any one regulation may not impose a significant burden on manufacturers,

[10] Available online at: *https://www.sba.gov/document/support—table-size-standards.*

the combined effects of several existing or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy conservation standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency.

Issue I.1 To the extent feasible, DOE seeks the names and contact information of any domestic or foreign-based manufacturers that distribute consumer refrigerators, refrigerator-freezers, and freezers in the United States.

Issue I.2 DOE identified small businesses as a subgroup of manufacturers that could be disproportionally impacted by amended energy conservation standards. DOE requests the names and contact information of small business manufacturers, as defined by the SBA's size threshold, of consumer refrigerators, refrigerator-freezers, and freezers that distribute products in the United States. In addition, DOE requests comment on any other manufacturer subgroups that could be disproportionally impacted by amended energy conservation standards. DOE requests feedback on any potential approaches that could be considered to address impacts on manufacturers, including small businesses.

Issue I.3 DOE requests information regarding the cumulative regulatory burden impacts on manufacturers of consumer refrigerators, refrigerator-freezers, and freezers associated with (1) other DOE standards applying to different products that these manufacturers may also make and (2) product-specific regulatory actions of other Federal agencies. DOE also requests comment on its methodology for computing cumulative regulatory burden and whether there are any flexibilities it can consider that would reduce this burden while remaining consistent with the requirements of EPCA.

J. Other Energy Conservation Standards Topics

1. Market Failures

In the field of economics, a market failure is a situation in which the market outcome does not maximize societal welfare. DOE welcomes comment on any aspect of market failures, especially those in the context of amended energy conservation standards for consumer refrigerators, refrigerator-freezers, and freezers.

2. Other

DOE welcomes comments on other issues relevant to the conduct of this rulemaking that may not specifically be identified in this document. In particular, DOE seeks comment on whether there have been sufficient technological or market changes since the most recent standards update that may justify a new rulemaking to consider more stringent standards. Specifically, DOE seeks data and information that could enable the agency to determine whether a more-stringent standard: (1) Would not result in significant additional savings of energy; (2) is not technologically feasible; (3) is not economically justified; or (4) any combination of the foregoing.

DOE also notes that under Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' Executive Branch agencies such as DOE are directed to manage the costs associated with the imposition of expenditures required to comply with Federal regulations. See 82 FR 9339 (February 3, 2017). Consistent with that Executive Order, DOE encourages the public to provide input on measures DOE could take to lower the cost of its energy conservation standards rulemakings, recordkeeping and reporting requirements, and compliance and certification requirements applicable to consumer refrigerators, refrigerator-freezers, and freezers while remaining consistent with the requirements of EPCA.

III. Submission of Comments

DOE invites all interested parties to submit in writing by December 30, 2019, comments and information on matters addressed in this RFI and on other matters relevant to DOE's consideration of amended energy conservations standards for consumer refrigerators, refrigerator-freezers, and freezers. After the close of the comment period, DOE will review the public comments received any may begin collecting data and conducting the analyses discussed in this RFI.

Submitting comments via *http://www.regulations.gov.* The *http://www.regulations.gov* web page requires you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies Office staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail. Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying

documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of the process for developing energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period in each stage of the rulemaking process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the rulemaking process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this process or would like to request a public meeting should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Signed in Washington, DC, on October 31, 2019.

Alexander N. Fitzsimmons,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2019–24820 Filed 11–14–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0538; Product Identifier 2012–NE–47–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: The FAA is revising an earlier proposal for certain Rolls-Royce plc (RR) RB211 Trent 768–60, 772–60, and 772B–60 model turbofan engines. This action revises the notice of proposed rulemaking (NPRM) by modifying the inspection threshold for ultrasonic inspections (UIs) of the affected low-pressure (LP) compressor blades for both standard operations and non-standard operations (NSO). This action also revises the service information references. The FAA is proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions would impose an additional burden over those in the NPRM, the FAA is reopening the comment period to allow the public the chance to comment on these changes.

DATES: The comment period for the NPRM published in the **Federal Register** on August 14, 2018 (83 FR 40161), is reopened.

The FAA must receive comments on this SNPRM by December 30, 2019.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202 493 2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12 140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this SNPRM, contact Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: 44 (0)1332 242424; fax: 44 (0)1332 249936; email: *https://www.rolls-royce.com/contact/civil_team.jsp.* You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0538; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this SNPRM, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Stephen Elwin, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7236; fax: 781–238–7199; email: *stephen.l.elwin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0538; Product Identifier 2012–NE–47–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this SNPRM. The FAA will consider all comments received by the closing date and may amend this SNPRM because of those comments.

The FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this SNPRM.

Discussion

The FAA issued an NPRM to amend 14 CFR part 39 by superseding AD 2017–03–02, Amendment 39–18793 (82 FR 10701, February 15, 2017), (''AD 2017–03–02'') that would apply to certain RR RB211 Trent 768–60, 772–60, and 772B–60 model turbofan engines. AD 2017–03–02 resulted from revised service information to reduce the inspection threshold of the UI for the LP compressor blades. The NPRM published in the **Federal Register** on August 14, 2018 (83 FR 40161). The NPRM was prompted by LP compressor blade partial airfoil release events. The NPRM proposed to require initial and repetitive UIs of the affected LP compressor blade and replacement of the LP compressor blade with a part eligible for installation if the LP compressor blade fails an inspection.

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2018–0188R1, dated September 5, 2018 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

> Occurrences have been reported of LP compressor partial aerofoil blade release events on RR Trent 700 engines. While primary containment of the released sections was achieved in each case, some of the releases did exhibit secondary effects that are considered to present a potential hazard.
>
> This condition, if not detected and corrected, could lead to LP compressor blade release with possible consequent loss of the engine nose cowl, under cowl fires and forward projection of secondary debris, possibly resulting in damage to the aeroplane and/or injury to persons on the ground.
>
> To address this potential unsafe condition, RR published NMSB RB.211–72–G872, providing inspection instructions and, consequently, EASA issued AD 2012–0247 to require a one-time inspection of the higher life LP compressor blades. After identification of a population of these LP compressor blades that were incorrectly inspected, RR issued NMSB RB.211–72–H311 and, consequently, EASA issued AD 2013–0060, retaining the requirements of EASA AD 2012–0247, which was superseded, to require a one-time re-inspection of the affected blades.
>
> After that AD was issued, to mitigate the risk of further partial LP compressor blade release events, RR issued NMSB RB.211–72–AH465, providing instructions for ultrasonic inspection of the affected parts to detect sub-surface anomalies in the aerofoil. Consequently, EASA issued AD 2014–0031, superseding [EASA] AD 2013–0060, to require repetitive inspections of all affected LP compressor blades and, depending on findings, replacement. Thereafter, EASA issued AD 2016–0141, retaining the requirements of [EASA] AD 2014–0031, which was superseded, to reduce inspection threshold (RR Alert NMSB RB.211–72–AH465 Revision 2). Prompted by further analysis, EASA issued AD 2017–0241, retaining the requirements of EASA AD 2016–0141, which was superseded, further reducing the inspection threshold and interval (RR Alert NMSB RB.211–72–AH465 Revision 4).
>
> Since EASA AD 2017–0241 was issued, RR issued the NMSB to distinguish between standard operations and NSO and to determine the applicable inspection threshold and interval. The flight cycles (FC) accumulated by operators conducting NSO have to be calculated using the beta factor shown in Table of the NMSB. The NMSB also introduces, for engines that have accumulated more than 600 FC or standard duty cycles (SDC, for engines used in NSO), a closing date by which these have to be inspected at least once.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2017–0241, which is superseded, and requires implementation of the changes introduced.

You may obtain further information by examining the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0538.

Actions Since the NPRM Was Issued

Since the FAA issued the NPRM, the manufacturer determined the need to modify the inspection threshold for UIs and to distinguish between operators conducting standard operations and NSO. The manufacturer also determined the need to require inspection of engines that have accumulated greater than 600 flight cycles (FCs) or standard duty cycles (SDCs) for engines used in NSO.

Also, since the FAA issued the NPRM, EASA issued EASA AD 2018–0188R1, dated September 5, 2018, which requires UIs of each affected LP compressor blade within the compliance time specified in the Accomplishment Instructions, paragraph 3, of RR Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AH465, Revision 5, dated July 26, 2018 (''the NMSB''). The FAA also determined the need to revise the references to the service information in this AD because, since the publication of the NPRM, RR published the NMSB.

Comments

The FAA gave the public the opportunity to comment on the NPRM. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Update Service Information

A commenter requested that the FAA update all service information references from RR Alert NMSB RB.211–72–AH465, Revision 4, to Revision 5. The commenter indicated that updated service information contains all the inspection compliance time and requirements as Revision 4, but Revision 5 also addresses NSO.

The FAA agrees to reference the latest revision of the service information in this proposed AD.

Support for the AD

The Air Line Pilots Association International supported the NPRM as written.

Related Service Information Under 1 CFR Part 51

The FAA reviewed RR Alert NMSB RB.211–72–AH465, Revision 5, dated July 26, 2018. The NMSB describes procedures for performing a UI of the LP compressor blades. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by EASA, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because it evaluated all the relevant information provided by EASA and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above expand the scope of the NPRM. As a result, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Proposed Requirements of This SNPRM

This SNPRM would require initial and repetitive UIs of the affected LP compressor blades and, depending on the results, their replacement with a part eligible for installation.

Costs of Compliance

The FAA estimates that this proposed AD affects 56 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect LP compressor blade	44 work-hours × $85 per hour = $3,740	$0	$3,740	$209,440

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. The FAA has no way of determining the number of engines that might need this replacement.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace LP compressor blade (one blade per 77 engine sets).	6 work-hours × $85 per hour = $510	$103,000	$103,510

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Rolls-Royce plc: Docket No. FAA–2018–0538; Product Identifier 2012–NE–47–AD.

(a) Comments Due Date

The FAA must receive comments by December 30, 2019.

(b) Affected ADs

This AD replaces AD 2017–03–02, Amendment 39–18793 (82 FR 10701, February 15, 2017).

(c) Applicability

This AD applies to Rolls-Royce plc (RR) RB211 Trent 768–60, 772–60, and 772B–60 turbofan engines, with low-pressure (LP) compressor blade, part number (P/N) FK23411, FK25441, FK25968, FW11901, FW15393, FW23643, FW23741, FW23744, KH23403, or KH23404, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by LP compressor blade partial airfoil release events. While released sections were contained in each case, projection of secondary debris and effects could present a potential hazard. The FAA is issuing this AD to prevent LP compressor blade airfoil separation. The unsafe condition, if not addressed, could result in damage to the engine and damage to the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) Within the compliance time specified in Figure 1 to paragraph (g)(1) of this AD and

thereafter, at intervals not to exceed 1,200 flight cycles (FCs) or Standard Duty Cycle (SDCs) for Non-Standard Operations (NSO), as applicable, since the last ultrasonic inspection (UI), perform a UI of each affected LP compressor blade in accordance with the Accomplishment Instructions, paragraph 3, of RR Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AH465, Revision 5, dated July 26, 2018.

Note 1 to paragraph (g): Paragraph 1.D of Rolls-Royce Alert NMSB RB.211–72–AH465, Revision 5, dated July 26, 2018, describes how to determine the applicable SDCs. The Time Limits Manual (TLM), 05–00–01, defines NSO.

Figure 1 to paragraph (g)(1) – Inspection Threshold

FCs/SDC Accumulated Since New or Since Last Inspection Required by paragraph (g)(1)	Compliance Times
Less than 1,100 FCs/SDCs	Before exceeding 1,200 FCs/SDCs since new.
1,100 FCs/SDCs or greater	Within 100 FCs/SDCs after the effective date of this AD, or before exceeding 2,400 FCs/SDCs since new, whichever occurs first.

(2) If, during any inspection required by paragraph (g)(1) of this AD, a LP compressor blade is rejected by the UI, as defined in Accomplishment Instructions, paragraph 3, of RR Alert NMSB RB.211–72–AH465, Revision 5, dated July 26, 2018, before further flight, or before returning the LP compressor blade to service, whichever occurs first, remove the affected LP compressor blade from service and replace with a part eligible for installation.

(h) Installation Prohibition

After the effective date of this AD, do not install an affected LP compressor blade on an engine unless the LP compressor blade meets the conditions specified in paragraphs (h)(1) or (2) of this AD, as applicable.

(1) The affected part has not exceeded 1,200 FC or SDCs (for NSO) since new, or since inspection in accordance with RR Alert NMSB RB.211–72–AH465, Revision 5, dated July 26, 2018, or since an inspection as specified in paragraph (k) of this AD, whichever occurs later.

(2) Prior to installation, the affected part has passed an ultrasonic inspection in accordance with paragraph (g)(1) of this AD.

(i) No Reporting Requirement

The reporting requirements in the Accomplishment Instructions, paragraph 3 of RR Alert NMSB RB.211–72–AH465, Revision 5, dated July 26, 2018, are not required by this AD.

(j) Credit for Previous Actions

You may take credit for LP compressor blade UIs required by paragraph (g)(1) of this AD, if you performed the UI before the effective date of this AD using:

(1) The instructions referenced in the mandatory inspection paragraph of the applicable engine TLM, provided the compliance times of this AD are not exceeded; or

(2) RR NMSB RB.211–72–G702, dated May 23, 2011; RR NMSB RB.211–72–G872, Revision 2, dated March 8, 2013, or earlier versions; RR NMSB RB.211–72–H311, dated March 8, 2013; RR NMSB RB.211–72–AH465, Revision 4, dated October 3, 2017, or earlier versions; Engine Manual E–Trent–1RR, Task 72–31–11–200–806; or Airbus A330 Aircraft Maintenance Manual (AMM) Task 72–31–41–270–801, or AMM Task 72–31–41–270–802.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ECO Branch, send it to the attention of the person identified in paragraph (l)(1) of this AD. You may email your request to: *ANE–AD–AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(l) Related Information

(1) For more information about this AD, contact Stephen Elwin, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7236; fax: 781–238–7199; email: *stephen.l.elwin@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2018–0188R1, dated September 5, 2018, for more information. You may examine the EASA AD in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2018–0538.

(3) For service information identified in this AD, contact Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: 44 (0)1332 242424; fax: 44 (0)1332 249936; email: *https://www.rolls-royce.com/contact/civil_team.jsp.* You may view this referenced service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759.

Issued in Burlington, Massachusetts, on November 6, 2019.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2019–24594 Filed 11–14–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0865; Product Identifier 2019–NM–158–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus SAS Model A350–941 and –1041 airplanes. This proposed AD was prompted by reports of passenger door girt bar fitting assembly safety hooks being stuck in the upward position. This proposed AD would require repetitive detailed inspections of girt bar fitting assemblies, repetitive greasing of girt bar fitting assembly bushes, and, depending

on findings, accomplishment of applicable corrective actions, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 30, 2019.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For the material identified in this proposed AD that will be incorporated by reference (IBR), contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0865.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0865; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0865; Product Identifier 2019–NM–158–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM based on those comments.

The FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this NPRM.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0207, dated August 22, 2019 (''EASA AD 2019–0207'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A350–941 and –1041 airplanes.

This proposed AD was prompted by reports of passenger door girt bar fitting assembly safety hooks being stuck in the upward position. The FAA is proposing this AD to address this condition, which could lead to girt bar disengagement from the girt bar fitting assembly and consequent failure of the passenger door slide deployment during an emergency, possibly preventing safe evacuation of the airplane. See the MCAI for additional background information.

Related IBR Material Under 1 CFR Part 51

EASA AD 2019–0207 describes procedures for repetitive detailed inspections of girt bar fitting assemblies, repetitive greasing of girt bar fitting assembly bushes, and, depending on findings, accomplishment of applicable corrective actions. Corrective actions include rework and replacement. EASA AD 2019–0207 also describes procedures for sending inspection results to Airbus. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to a bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2019–0207 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2019–0207 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2019–0207 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in the EASA AD. Service information specified in EASA AD 2019–0207 that is required for compliance with EASA AD 2019–0207 will be available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0865 after the FAA final rule is published.

Interim Action

The FAA considers this proposed AD interim action. If final action is later identified, the FAA might consider further rulemaking then.

Costs of Compliance

The FAA estimates that this proposed AD affects 13 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS *

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$1,105

*Table does not include estimated costs for reporting.

The FAA estimates that it would take about 1 work-hour per product to comply with the proposed reporting requirement in this proposed AD. The average labor rate is $85 per hour. Based on these figures, the FAA estimates the cost of reporting the inspection results on U.S. operators to be $1,105, or $85 per product.

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 3 work-hours × $85 per hour = $255	*	*$255

*The FAA has received no definitive data that would enable the agency to provide parts cost estimates for the on-condition actions specified in this proposed AD.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this NPRM is 2120–0056. The paperwork cost associated with this NPRM has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this NPRM is mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus SAS: Docket No. FAA–2019–0865; Product Identifier 2019–NM–158–AD.

(a) Comments Due Date

The FAA must receive comments by December 30, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Reason

This AD was prompted by reports of passenger door girt bar fitting assembly safety hooks being stuck in the upward position. We are issuing this AD to address this condition, which could lead to girt bar disengagement from the girt bar fitting assembly and consequent failure of the passenger door slide deployment during an emergency, possibly preventing safe evacuation of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2019–0207, dated August 22, 2019 (''EASA AD 2019–0207'').

(h) Exceptions to EASA AD 2019–0207

(1) Where EASA AD 2019–0207 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2019–0207 does not apply to this AD.

(3) Paragraph (4) of EASA AD 2019–0207 specifies to report inspection results to Airbus within a certain compliance time. For this AD, report inspection results at the applicable time specified in paragraph (h)(3)(i) or (ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 90 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 90 days after the effective date of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC)*: For any service information referenced in EASA AD 2019–0207 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(4) *Paperwork Reduction Act Burden Statement:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

(j) Related Information

(1) For information about EASA AD 2019–0207, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu;* Internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0865.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

Issued in Des Moines, Washington, on November 1, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–24532 Filed 11–14–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0864; Product Identifier 2019–NM–140–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus SAS Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes); and Model A310 series airplanes. This proposed AD was prompted by a determination that new tests are necessary to address potential air leaks in the reservoir air pressurization lines. This proposed AD would require repetitive pressurization tests of the reservoir air pressurization lines for pipe rupture and leaks, and repair or replacement if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 30, 2019.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For the material identified in this proposed AD that will be incorporated by reference (IBR), contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0864.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0864; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0864; Product Identifier 2019–NM–140–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM based on those comments.

The FAA will post all comments, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact the agency receives about this NPRM.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0188, dated July 31, 2019 (''EASA AD 2019–0188'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes); Model A310 series airplanes; and Model A300F4–608ST airplanes. (Model A300F4–608ST airplanes are not on the U.S. Register; this proposed AD therefore does not include those airplanes in the applicability.)

This proposed AD was prompted by a determination that new tests are necessary to address potential air leaks in the reservoir air pressurization lines. The FAA is proposing this AD to address air leaks that could result in the loss of a hydraulic system and consequent reduced controllability of the airplane. See the MCAI for additional background information.

Related IBR Material Under 1 CFR Part 51

EASA AD 2019–0188 describes airworthiness limitations involving repetitive pressurization tests of the reservoir air pressurization lines for pipe rupture and leaks, and repair and replacement of affected hydraulic pipes, ducts, and pressurization lines. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2019–0188 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2019–0188 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2019–0188 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in the EASA AD. Service information specified in EASA AD 2019–0188 that is required for compliance with EASA AD 2019–0188 will be available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0864 after the FAA final rule is published.

Interim Action

The FAA considers this proposed AD interim action. If final action is later identified, the FAA might consider further rulemaking then.

Costs of Compliance

The FAA estimates that this proposed AD affects 123 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × $85 per hour = 170 per inspection cycle	$0	$170 per inspection cycle	$20,910 per inspection cycle.

The FAA estimates the following costs to do any necessary on-condition action that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
3 work-hours × $85 per hour = $255	$0	$255

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus SAS: Docket No. FAA–2019–0864; Product Identifier 2019–NM–140–AD.

(a) Comments Due Date

The FAA must receive comments by December 30, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model airplanes specified in paragraphs (c)(1) through (5) of this AD, certificated in any category.

(1) Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes.

(2) Model A300 B4–605R and B4–622R airplanes.

(3) Model A300 F4–605R and F4–622R airplanes.

(4) Model A300 C4–605R Variant F airplanes.

(5) Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic power.

(e) Reason

This AD was prompted by a determination that new tests are necessary to address potential air leaks in the reservoir air pressurization lines. The FAA is issuing this AD to address air leaks that could result in the loss of a hydraulic system and consequent reduced controllability of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2019–0188, dated July 31, 2019 (''EASA AD 2019–0188'').

(h) Exceptions to EASA AD 2019–0188

(1) Where EASA AD 2019–0188 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2019–0188 does not apply to this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may

be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2019–0188 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

(1) For information about EASA AD 2019–0188, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0864.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

Issued in Des Moines, Washington, on November 1, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–24531 Filed 11–14–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

48 CFR Part 2902

[DOL Docket No. DOL–2019–0002]

RIN 1291–AA42

Department of Labor Acquisition Regulations: Definitions for Head of Agency, Head of Contracting Activity, and Senior Procurement Executive

AGENCY: Office of the Assistant Secretary for Administration and Management, Department of Labor.

ACTION: Proposed rule; withdrawal.

SUMMARY: With this notice, the Department of Labor (Department) is withdrawing the proposed rule that accompanied its direct final rule (DFR) amending three definitions in the Department of Labor Acquisition Regulation (DOLAR) in order to provide the Secretary of Labor greater flexibility and a streamlined procedure to delegate procurement authority and appoint procurement officials.

DATES: The proposed rule published August 29, 2019 (84 FR 45456) is withdrawn as of November 15, 2019.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Ms. Megan P. Sweeney, Office of Public Affairs, Room No. S–2514, U.S. Department of Labor, 200 Constitution Ave. NW, Washington, DC 20210; telephone: (202) 693–4676; email: *sweeney.megan.p@dol.gov.*

General information: Herman J. Narcho, U.S. Department of Labor, Office of the Assistant Secretary for Administration and Management, Office of the Chief Procurement Officer, 200 Constitution Avenue NW, Room N–5305, Washington, DC 20210; telephone (202) 693–7171 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On August 29, 2019, the Department published a proposed rule amending three DOLAR definitions found at 48 CFR 2902.101(b): Head of Agency, Head of Contracting Activity, and Senior Procurement Executive. The Department published a companion DFR rule proposing the same changes to the DOLAR definitions. In the DFR, the Department stated that it would withdraw the companion proposed rule and confirm the effective date of the DFR if no significant adverse comments were submitted on the DFR by September 30, 2019. The Department received no comments on the proposed rule. Accordingly, the Department is not proceeding with the proposed rule and is withdrawing it from the rulemaking process.

List of Subjects in 48 CFR Part 2902

Government procurement.

Bryan Slater,

Assistant Secretary for Administration and Management, Labor.

[FR Doc. 2019–24681 Filed 11–14–19; 8:45 am]

BILLING CODE 4510–04–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 622 and 635

[Docket No. 191101–0072]

RIN 0648–BI61

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Atlantic Highly Migratory Species; Coral and Coral Reefs of the Gulf of Mexico; Amendment 9

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in Amendment 9 to the Fishery Management Plan (FMP) for the Coral and Coral Reefs of the Gulf of Mexico (Amendment 9) and an associated framework action to the FMP, as prepared by the Gulf of Mexico Fishery Management Council (Council). This proposed rule would establish new habitat areas of particular concern (HAPCs), some of which include a prohibition of the deployment of bottom-tending gear, and modify current fishing regulations for the other existing HAPCs in the Gulf of Mexico (Gulf). Additionally, this proposed rule would implement complementary management measures for Atlantic highly migratory species (HMS) in the Gulf. The purpose of this proposed rule is to protect coral essential fish habitat in the Gulf.

DATES: Written comments must be received by December 16, 2019.

ADDRESSES: You may submit comments on this proposed rule identified by ''NOAA–NMFS–2017–0146'' by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2017-0146,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Lauren Waters, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of Amendment 9 and the framework action may be obtained from *www.regulations.gov* or the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/amendment-9-coral-habitat-areas-considered-management-gulf-mexico.* Amendment 9 includes a final environmental impact statement (EIS), fishery impact statement, regulatory impact review, and a Regulatory Flexibility Act (RFA) analysis.

FOR FURTHER INFORMATION CONTACT: Lauren Waters, NMFS Southeast Regional Office, telephone: 727–824–5305; email: *lauren.waters@noaa.gov.* Karyl Brewster-Geisz, NMFS Highly Migratory Species Division, telephone: 301–427–8503; email: *karyl.brewster-geisz@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS and the Council manage coral and coral reef resources in the Gulf under the FMP. The FMP was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). NMFS manages Atlantic HMS under the 2006 Consolidated Atlantic HMS FMP and its amendments, under the authority of the Magnuson-Stevens Act and the Atlantic Tunas Convention Act. The 2006 Consolidated Atlantic HMS FMP is implemented by regulations at 50 CFR part 635.

Background

The Magnuson-Stevens Act requires that each fishery management plan identify and describe essential fish habitat (EFH) and minimize, to the extent practicable, adverse effects on these habitats caused by fishing. The FMP describes coral EFH as those areas where managed corals exist. HAPCs are a subset of EFH that meet specified criteria identified at 50 CFR 600.815(a)(8). An area in which corals exist in sufficient numbers or diversity could be designated as an HAPC if it is significantly ecologically important, habitat that is sensitive to human-induced degradation, located in an environmentally stressed area, or considered rare in abundance. Corals and coral habitat are especially sensitive to human-induced degradation by fishing and non-fishing activities because of their unique life history. An HAPC designation by NMFS does not confer any additional specific protections to such designated areas, but can be used to focus management attention on those areas when considering measures to minimize adverse impacts from fishing.

In December 2014, the Council convened a Coral Working Group to discuss which areas in the Gulf may warrant additional specific protection for corals. The group identified numerous new areas and existing HAPCs that may be in need of new or revised protection. In May 2015, the Council's Special Coral Scientific and Statistical Committee (SSC) and Coral Advisory Panel (AP) reviewed these areas along with members of the shrimp fishing community and recommended that the boundaries of some of the areas be refined based on available fishing information. In August 2016, the Council's Coral SSC, Coral AP, Shrimp AP, as well as Council invitees, which included royal red shrimp fishermen and bottom longline fishermen, provided input to the Council. These groups recommended that 15 new areas be designated as HAPCs in which fishing with bottom-tending gear be prohibited and 8 areas be designated as HAPCs without any prohibitions on fishing. Based on this input, the Council began developing Amendment 9. On December 18, 2017, NMFS published a notice of intent to prepare a draft EIS for Amendment 9 in the **Federal Register** and solicited public comment (82 FR 60003).

In April 2018, based on a recommendation by the Council's SSC, the Council modified the alternatives in Amendment 9 to combine three previously proposed HAPCs in the southeastern Gulf that were separate but geographically close to one another into a single slightly smaller proposed HAPC. As a result, Amendment 9 recommends 13 new HAPCs in which fishing with bottom-tending gear would be prohibited.

During subsequent discussions associated with Amendment 9, the Council decided to refine the fishing prohibition in the proposed and existing HAPCs. The Council determined that the broad definition of ''fishing'' in the Magnuson-Stevens Act might unnecessarily restrict activities that would have no impact on these HAPCs. Therefore, in August 2018, the Council approved a framework action that would modify the specific prohibitions on ''fishing with bottom-tending gear'' to ''deployment of bottom-tending gear'' for existing HAPCs listed in 50 CFR 622.74, except the Tortugas marine reserves HAPC, and those recommended in Amendment 9. Further, the Council recommended that ''deploy'' in this context be defined to mean that fishing gear is in contact with the water. In November 2018, the Council also requested that NMFS develop complimentary gear deployment prohibitions for Atlantic HMS fisheries in the Gulf (see 50 CFR part 635).

The management actions selected by the Council in Amendment 9 and as subsequently modified in the framework action are described in this proposed rule.

Management Measure Contained in This Proposed Rule

This proposed rule would establish 13 new HAPCs in the Gulf in which the deployment of certain bottom-tending gears would be prohibited. The proposed rule would also prohibit the deployment of dredge fishing gear in existing Gulf HAPCs that are managed with fishing regulations. Further, this proposed rule would modify the restrictions in the existing HAPCs that prohibit fishing with specific gears to prohibit the deployment of those gears. NMFS and the Council are proposing these areas and fishing regulations to protect coral EFH in the Gulf.

HAPCs With Fishing Regulations

This proposed rule would establish 13 HAPCs in which the deployment of specified bottom-tending gear would be prohibited. For purpose of the prohibition, fishing gear is ''deployed'' if any part of the gear is in contact with the water. The 13 proposed HAPCs are called West Florida Wall, Alabama Alps Reef, L & W Pinnacles and Scamp Reef (combined), Mississippi Canyon 118, Roughtongue Reef, Viosca Knoll 826, Viosca Knoll 862/906, AT 047, AT 357, Green Canyon 852, Southern Bank, Harte Bank, and Pulley Ridge South Portion A. Pulley Ridge South Portion A is adjacent to the current Pulley Ridge South HAPC.

For these areas, excluding Pulley Ridge South Portion A, prohibitions on the following activities would apply year-round: Deployment of bottom

longline, bottom trawl, buoy gear as defined in 50 CFR 622.2, dredge, pot, or trap, and bottom anchoring by fishing vessels. The buoy gear defined in 50 CFR 622.2 is not the same as HMS buoy gear defined in 50 CFR 635.2. HMS buoy gear is not a bottom-tending gear.

Within the proposed Viosca Knoll 862/906 area, the proposed gear deployment prohibitions would not apply to a fishing vessel issued a Gulf royal red shrimp endorsement, as specified in 50 CFR 622.50(c) while fishing for royal red shrimp. The areas around this proposed HAPC are used to fish for royal red shrimp. Fishing for royal red shrimp occurs in deep waters and requires a few miles of continuous forward movement to lift the nets up in the water column to the vessel. Therefore, requiring that these nets be out of the water would effectively prevent the use of an area much larger than the proposed HAPC. The exemption would allow royal red shrimp fishermen to continue the historic practice of lifting the nets off the bottom but keeping them in the water as they travel through this area.

Within the proposed Pulley Ridge South Portion A area, the following prohibitions would apply year-round: Deployment of a bottom trawl, buoy gear as defined in 50 CFR 622.2, dredge, pot, or trap, and bottom anchoring by fishing vessels. Pulley Ridge South Portion A would not include a restriction on the deployment of bottom longline gear to allow fishing that has historically occurred in this area to continue. This proposed rule would not change any other boundaries or regulations within the existing Pulley Ridge HAPC.

The Council concluded that the exception for royal red shrimp fishing in the proposed Viosca Knoll 862/906 area and for bottom longline fishing in the proposed Pulley Ridge South Portion A area was unlikely to adversely affect the habitat. Both types of fishing have occurred in the respective areas for over a decade without causing significant harm.

Dredge Fishing Prohibition

Currently, only some existing HAPCs in the Gulf have fishing regulations that prohibit dredge fishing within the designated areas. This proposed rule would prohibit the deployment of dredge fishing gear in all existing HAPCs in the Gulf in which other bottom-tending gear are already prohibited. Dredge fishing is most commonly used to harvest shellfish and is not known to occur in the Gulf. Therefore, this proposed management measure would not restrict any known fishing activity in the Gulf, but increase consistency of management measures across HAPCs with fishing regulations.

Fishing Restrictions in Existing HAPCs

This proposed rule would modify restrictions associated with bottom-tending fishing gear in the existing HAPCs. Currently, the regulations at 50 CFR 622.74 prohibit ''fishing'' in the existing HAPCs with bottom-tending gear with specific types of gear prohibitions varying by HAPC. As explained above, the Council determined that it was more appropriate to prohibit the ''deployment'' of bottom-tending gear. Therefore, this proposed rule would change the prohibition for existing HAPCs listed in 50 CFR 622.74, other than the Tortugas marine reserves HAPC, to prevent the deployment of the bottom-tending gear to be consistent with the prohibition in the proposed HAPCs. The Tortugas marine reserves HAPC already has a broader prohibition on all fishing and anchoring by fishing vessels.

HMS Fisheries in the Gulf

This proposed rule would modify regulations at 50 CFR 635.21 for Atlantic HMS fisheries that operate in the Gulf to complement the proposed fishing vessel anchoring and gear deployment prohibitions in 50 CFR 622.74.

Management Measure Contained in Amendment 9 But Not Codified Through This Proposed Rule

Amendment 9 would also establish eight HAPCs with no associated fishing regulations. The Council determined that fishing regulations in these eight proposed HAPCs are unnecessary because there is no known fishing activity that occurs within them, partly because the areas are located in very deep water (greater than 984 ft or 300 m). The proposed HAPCs without fishing regulations in Amendment 9 are South John Reed, Garden Banks 299, Garden Banks 535, Green Canyon 140 and 272 (combined), Green Canyon 234, Green Canyon 354, Mississippi Canyon 751, and Mississippi Canyon 885. Although fishing impacts were not identified as a concern in these eight areas, establishing these HAPCs would inform the public that the Council considers these areas to be of particular importance and could help guide NMFS' review of non-fishing impacts during EFH consultations.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with Amendment 9, the FMP for the Coral and Coral Reefs of the Gulf of Mexico, the 2006 Consolidated FMP for Atlantic Highly Migratory Species, the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866. This proposed rule is not an Executive Order 13771 regulatory action because this proposed rule is not significant under Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination follows.

A description of the proposed rule, why it is being considered, and the objectives of, and legal basis for this proposed rule are contained in the preamble of this proposed rule at the beginning of the **SUPPLEMENTARY INFORMATION** section and in the **SUMMARY** section. The Magnuson-Stevens Act provides the statutory basis for this proposed rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this proposed rule. Accordingly, the requirements of the Paperwork Reduction Act do not apply to this proposed rule.

The proposed action would designate several areas in the Gulf as HAPCs and establish or modify fishing regulations in new and existing HAPCs. In some of the proposed HAPCs the deployment of specific bottom-tending gear would be prohibited. The proposed action would also change the prohibition in the existing HAPCs with fishing regulations to a prohibition on the deployment of the gear as opposed to fishing with the gear. As a result, this proposed action would directly affect federally permitted commercial fishermen fishing for reef fish, shrimp, or sharks. Recreational anglers fishing in the designated HAPCs would also be directly affected by this proposed action, but anglers are not considered business entities under the RFA. Recreational charter vessels and headboats would also be affected by this action but only in an indirect way. Thus, only the effects on federally permitted commercial fishing vessels harvesting reef fish, shrimp, and shark will be discussed. For RFA purposes only, NMFS has established a small

business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide.

To determine whether a substantial number of small entities would be affected by the proposed rule, NMFS first describes the characteristics of the Federal commercial reef fish, shrimp, and shark fisheries that operate in the Gulf. NMFS then describes the data available to determine the number of small entities that operate in the proposed HAPCs and applies these data to each proposed HAPC or groups of HAPCs.

With respect to the Gulf reef fish fishery, as of July 14, 2018, there were 841 vessels with valid or renewable Federal Gulf reef fish commercial vessel permits. From 2010 through 2016, an average of 554 federally permitted commercial reef fish vessels per year landed any reef fish species in the Gulf. These vessels, combined, averaged 6,608 trips per year in the Gulf on which reef fish were landed and 810 other trips. The average annual total dockside revenue (2016 dollars) for these vessels combined was approximately $52.13 million from reef fish, approximately $1.32 million from other species co-harvested with reef fish (on the same trips), and approximately $1.54 million from other trips by these vessels in the Gulf on which no reef fish were harvested or where fishing occurred in other areas. Total average annual revenue from all species harvested by these vessels in the Gulf or other areas was approximately $54.95 million, or approximately $99,000 per vessel. These vessels generated approximately 95 percent of their total revenues from reef fish. Commercial reef fish vessels used a variety of gears in harvesting reef fish. For the period 2010–2016, an average of 68 vessels used longlines and generated revenues of approximately $250,000 per vessel; 267 vessels used bandit gear generating approximately $109,000 revenue per vessel; 273 vessels used hook-and-line generating approximately $27,000 revenue per vessel; 47 vessels used diving gear generating approximately $13,000 revenue per vessel; and, 6 vessels used other gears generating approximately $40,000 revenue per vessel. Therefore, all federally permitted commercial vessels fishing for reef fish are assumed to be small entities.

In the Gulf shrimp fishery, brown and white shrimp are the dominant shrimp species in terms of landings, ex-vessel revenues, and number of participating vessels. For the period 2010–2016, an annual average of 3,552 vessels landed approximately 61 million lb (27,669,134 kg) of brown shrimp with an ex-vessel value of about $206 million; an annual average of 3,914 vessels landed approximately 61 million lb (27,669,134 kg) of white shrimp valued at about $210 million; an annual average of 175 vessels landed pink shrimp valued at about $18 million; and, an annual average of 8 vessels landed approximately 154,000 lb (69,853 kg) of royal red shrimp valued at about $964,000. Not all vessels that landed Gulf shrimp are federally permitted, and not all federally permitted vessels landed shrimp. In 2014, for example, only 74 percent of federally permitted vessels landed shrimp. As of July 14, 2018, there were 1,422 valid or renewable Gulf shrimp commercial permits and 305 valid Gulf royal red shrimp endorsements. The latest data on the economics and financial conditions of the Gulf shrimp fishery are for 2014. Data for later years are still being processed and compiled by NMFS. Between 2011 and 2014, the average gross revenue from fishing operations of federally permitted shrimp vessels was approximately $343,000, but net revenue from operations was only about $8,300. These estimates best approximate expected financial and economic conditions for these vessels in the foreseeable future. Therefore, all federally permitted commercial vessels fishing for shrimp are assumed to be small entities.

The HMS shark fishery is the fishery that most likely would be affected by the proposed action. To commercially fish for sharks, fishermen need to possess a Federal shark directed or incidental permit, or smoothhound shark permit. Shark directed and incidental permits are currently limited access permits, while the smoothhound shark permit is an open access permit. As of September 12, 2018, there were 220 and 267 valid or renewable shark directed and incidental permits, respectively, and 164 valid or renewable smoothhound shark permits. Vessels can possess shark permits in addition to commercial reef fish or shrimp permits. In 2017, there were 18 vessels with limited access permits that were actively fishing for sharks in the Gulf. Of the 18 vessels, 11 possessed both a shark limited access permit and a commercial reef or shrimp permit, while 7 possessed only a shark limited access permit. These vessels, combined, generated $4.7 million of revenue from HMS. When tracked back to 2013, these vessels generated an average revenue of $4.8 million per year, indicating a close match between their 2017 revenue and 2013–2017 average revenue. The 2013–2017 average revenue per vessel was approximately $267,000. Therefore, all federally permitted commercial vessels fishing for sharks are assumed to be small entities.

As stated earlier in the preamble, the proposed rule would establish 13 HAPCs in which the deployment of specific bottom-tending gear would be prohibited. Unless otherwise noted, the following prohibitions would apply to each of the 13 HAPCs: Deployment of bottom longline, bottom trawl, buoy gear as defined in 50 CFR 622.2, dredge, pot, or trap, and bottom anchoring by fishing vessels.

The available data allows NMFS to estimate the number of federally permitted reef fish, shrimp, and shark vessels potentially affected by the proposed rule. Information on fishing activities in the proposed HAPCs is based on the electronic logbook (ELB) program for commercial shrimp vessels, the vessel monitoring system (VMS) for commercial reef fish vessels, and shark bottom longline observer program (SBLOP) for shark vessels. Available ELB data are for the years 2004–2013, VMS data are for the years 2007–2015, and SBLOP data are for the years 2008–2016.

ELB data are collected from approximately one-third of the federally permitted shrimp vessels, while VMS data collection is required of all federally permitted reef fish vessels. Vessels that were included in the SBLOP are also in the VMS data set because these vessels have both shark and commercial reef fish permits. The VMS and ELB data sets provide data points and number of fishing vessels by area, while the SBLOP data provides some information on the number of fishing sets by shark vessels. Although VMS data are collected from all reef fish vessels, the points refer to the number of times the electronic system detects the vessel in a specific area, but it does not distinguish between fishing and non-fishing activity. In contrast, ELB data points are collected from approximately one-third of permitted shrimp vessels but this occurs every 10 minutes, which allows NMFS to determine likely fishing activity from non-fishing activity based on vessel speed. Therefore, the ELB data points in this analysis are those that NMFS has

determined to represent active shrimp fishing.

Because the VMS, ELB, and SBLOP data sources do not provide information on the number of trips or fishing intensity per vessel, it is not possible to estimate the revenue and profit effects of the proposed rule. Therefore, the extent of economic impacts is based on the number of vessels potentially affected by the proposed rule. In the following discussion, data points and vessels are expressed as annual averages for each of the 13 proposed HAPCs. In addition, only information on bottom longline vessels from VMS data is reported as only these vessels would likely be affected by the proposed rule.

In the Pulley Ridge South Portion A HAPC, ELB data indicate one data point corresponding to one shrimp vessel. VMS data indicate 638 data points corresponding to 11 bottom longline vessels. However, to allow fishing that has historically occurred to continue, the proposed regulations would not prohibit the deployment of bottom longlines. Therefore, longline vessels would not be affected by the gear prohibitions in this area. SBLOP recorded only two fishing sets by shark longline vessels, which are included in the VMS data set. Based on the above information, the gear prohibitions in this area would not affect a substantial number of small entities.

For the West Florida Wall HAPC, which is located in the southeastern Gulf, ELB did not record any data point or shrimp vessel fishing in the proposed area. VMS recorded 4 data points corresponding to two bottom longline vessels. SBLOP data indicate very low shark fishing effort in the area. Therefore, the proposed gear prohibitions in this area would not affect a substantial number of small entities.

Six new HAPCs would be established in the northeastern Gulf: Alabama Alps Reef, L & W Pinnacles and Scamp Reef, Mississippi Canyon 118, Roughtongue Reef, Viosca Knoll 826, and Viosca Knoll 862/906. For Alabama Alps Reef, ELB recorded one data point corresponding to one vessel and VMS recorded seven data points and one bottom longline vessel. For L & W Pinnacles and Scamp Reef, ELB recorded 2 data points and 1 vessel while VMS recorded 42 data points 3 bottom longline vessels. For Mississippi Canyon 118, ELB recorded four data points and one vessel while VMS recorded four data points and one bottom longline vessel. For Roughtongue Reef, ELB recorded 1 data point and 1 vessel while VMS recorded 40 data points and 3 bottom longline vessels. For Viosca Knoll 826, ELB recorded one data point and one vessel while VMS recorded one data point and one bottom longline vessel. For Viosca Knoll 862/906, ELB recorded 168 data points and 2 vessels while VMS recorded 8 data points and 2 bottom longline vessels. NMFS notes that shrimp vessels fishing in Viosca Knoll 862/906 are mainly those fishing for royal red shrimp. Vessels with a royal red shrimp endorsement fishing for this species in this area are exempt from the prohibition on bottom-tending gear and would not be affected by this proposed rule. SBLOP reported only two sets by two shark fishing vessels for L & W Pinnacles and Scamp Reef, and none for the other areas. Because of the general location of this group of HAPCs, it is likely that certain vessels could be fishing in multiple HAPCs within this group in any given year. It is also possible that a vessel would fish in different HAPCs from year to year. Thus, the total number of vessels affected by the proposed prohibitions applicable in this group of HAPCs would be less than the sum of vessels fishing in each HAPC as noted above. Therefore, the gear prohibitions in these six areas would not affect a substantial number of small entities.

The proposed rule would establish three new HAPCs in the northwestern Gulf: AT 047, AT 357, and Green Canyon 852. Both ELB and VMS recorded very few data points and vessels fishing in each of these three areas. ELB recorded at most one data point and one vessel for each of these three areas while VMS recorded at most one data point and one bottom longline vessel in each of the AT 047 and AT 357 HAPCs and none for Green Canyon 852. In addition, no shark fishing sets were observed in these areas. Therefore, the gear prohibitions in these three areas would not affect a substantial number of small entities.

The proposed rule would establish two new HAPCs in the southwestern Gulf: Harte Bank and Southern Bank. ELB recorded at most one data point and one vessel while VMS recorded at most one data point and one bottom longline vessel for Harte Bank HAPC. ELB recorded one data point and one vessel, while VMS recorded no data points or bottom longline vessels for the Southern Bank HAPC. In addition, no bottom longlining for sharks was observed in these two areas. Therefore, the gear prohibitions in these two areas would not affect a substantial number of small entities.

The proposed action to change the prohibition in the existing HAPCs with fishing regulations to a prohibition on the ''deployment'' of bottom-tending gear, as opposed to a prohibition on ''fishing'' with the bottom-tending gear, would have no effects on the revenues of fishing vessels. These vessels do not currently derive any revenues from fishing with bottom-tending gear in any existing HAPCs with fishing regulations. This proposed action would make fishing regulations in existing HAPCs consistent with the regulations in the proposed new HAPCs, and therefore would lessen confusion on the part of fishermen as well as simplify enforcement.

Amendment 9 would also establish eight new deep-water HAPCs without fishing regulations, which would have no accompanying economic effects on small entities. The effects of prohibiting the deployment of dredge fishing gear in all HAPCs that have fishing regulations are included in the discussion of effects for each HAPC. This prohibition would not impact any small entities as there is no known dredge fishing in any existing or proposed HAPCs.

In summary, there are three Federal fisheries that operate in the proposed HAPCs, and although all of the commercially permitted reef fish, shrimp, and shark vessels are small entities, based on available data only a small number of vessels are estimated to have fished with bottom-tending gear in each of the proposed HAPCs, and all HAPCs combined. Therefore, this proposed rule would not affect a substantial number of small entities.

The information provided above supports a determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. Because this proposed rule, if implemented, is not expected to have a significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects

50 CFR Part 622

Coral, Fisheries, Fishing, Gulf of Mexico.

50 CFR Part 635

Fisheries, Fishing, Fishing vessels, Foreign relations, Imports, Penalties, Reporting and recordkeeping requirements, Treaties.

Dated: November 4, 2019.

Samuel D. Rauch III,

Deputy Assistant Administrator, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 622 and 635 are proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. Section 622.74 is revised to read as follows:

§ 622.74 Area closures to protect Gulf corals.

For the purposes of this section, fishing gear is deployed if any part of the gear is in contact with the water.

(a) *Florida Middle Grounds HAPC.* Deployment of a bottom longline, bottom trawl, dredge, pot, or trap is prohibited year-round in the area bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (a)

Point	North lat.	West long.
A	28°42.500′	84°24.800′
B	28°42.500′	84°16.300′
C	28°11.000′	84°00.000′
D	28°11.000′	84°07.000′
E	28°26.600′	84°24.800′
A	28°42.500′	84°24.800′

(b) *Tortugas marine reserves HAPC.* Fishing for any species and bottom anchoring by fishing vessels are prohibited year-round in the areas of the HAPC.

(1) *EEZ portion of Tortugas North HAPC.* The area is bounded by rhumb lines connecting the following points in order: From point A at 24°40.000′ N lat., 83°06.000′ W long. to point B at 24°46.000′ N lat., 83°06.000′ W long. to point C at 24°46.000′ N lat., 83°00.000′ W long.; then along the line denoting the seaward limit of Florida's waters, as shown on the current edition of NOAA chart 11434, to point A at 24°40.000′ N lat., 83°06.000′ W long.

(2) *Tortugas South HAPC.* The area is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (b)(2)

Point	North lat.	West long.
A	24°33.000′	83°09.000′
B	24°33.000′	83°05.000′
C	24°18.000′	83°05.000′
D	24°18.000′	83°09.000′
A	24°33.000′	83°09.000′

(c) *Pulley Ridge South HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the area of the HAPC bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (c)

Point	North lat.	West long.
A	24°58.300′	83°38.550′
B	24°58.300′	83°37.000′
C	24°41.183′	83°37.000′
D	24°40.000′	83°41.367′
E	24°43.917′	83°47.250′
A	24°58.300′	83°38.550′

(d) *Pulley Ridge South Portion A HAPC.* Deployment of a bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the area of the HAPC bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (d)

Point	North lat.	West long.
A	24°40.000′	83°41.366′
B	24°39.666′	83°42.648′
C	24°47.555′	83°55.240′
D	24°57.065′	83°48.405′

TABLE 1 TO PARAGRAPH (d)—Continued

Point	North lat.	West long.
E	24°52.859′	83°41.841′
F	24°43.917′	83°47.250′
A	24°40.000′	83°41.366′

(e) *West Florida Wall HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the area of the HAPC bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (e)

Point	North lat.	West long.
A	26°28.835′	84°47.955′
B	26°28.816′	84°46.754′
C	26°10.471′	84°42.076′
D	26°10.528′	84°44.577′
E	26°25.028′	84°47.986′
F	26°25.100′	84°47.980′
A	26°28.835′	84°47.955′

(f) *Alabama Alps Reef HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the area of the HAPC bounded by rhumb lines connecting the following points in:

TABLE 1 TO PARAGRAPH (f)

Point	North lat.	West long.
A	29°16.160′	88°20.525′
B	29°15.427′	88°18.990′
C	29°13.380′	88°19.051′
D	29°14.140′	88°20.533′
A	29°16.160′	88°20.525′

(g) *L & W Pinnacles and Scamp Reef HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the area of the HAPC bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (g)

Point	North lat.	West long.
A	29°18.595′	87°48.757′
B	29°18.484′	87°50.688′
C	29°19.754′	87°52.484′
D	29°20.401′	87°51.449′
E	29°20.095′	87°50.933′
F	29°20.832′	87°46.631′
G	29°21.473′	87°46.326′
H	29°21.314′	87°45.535′
I	29°22.518′	87°43.465′
J	29°21.144′	87°42.632′
K	29°19.269′	87°45.525′
A	29°18.595′	87°48.757′

(h) *Mississippi Canyon 118 HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the area of the HAPC bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (h)

Point	North lat.	West long.
A	28°53.183′	88°30.789′
B	28°53.216′	88°27.819′
C	28°50.602′	88°27.782′
D	28°48.944′	88°27.759′
E	28°48.962′	88°30.727′
A	28°53.183′	88°30.789′

(i) *Roughtongue Reef HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the area of the HAPC bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (i)

Point	North lat.	West long.
A	29°27.596′	87°37.527′
B	29°27.621′	87°31.552′
C	29°25.007′	87°31.539′
D	29°24.981′	87°37.510′
A	29°27.596′	87°37.527′

(j) *Viosca Knoll 826 HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the area of the HAPC bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (j)

Point	North lat.	West long.
A	29°10.920′	88°03.509′
B	29°10.877′	87°59.460′
C	29°07.974′	87°59.448′
D	29°08.017′	88°03.532′
A	29°10.920′	88°03.509′

(k) *Viosca Knoll 862/906 HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the area of the HAPC. This prohibition does not apply to a fishing vessel issued a Gulf royal red shrimp endorsement, as specified in § 622.50(c), while the vessel is fishing for royal red shrimp. The HAPC is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (k)

Point	North lat.	West long.
A	29°07.640′	88°23.608′
B	29°07.603′	88°20.590′
C	29°03.749′	88°20.554′
D	29°03.734′	88°22.016′
E	29°02.367′	88°21.998′
F	29°02.281′	88°24.972′
G	29°07.568′	88°25.044′
H	29°07.592′	88°25.044′
I	29°07.676′	88°25.045′
A	29°07.640′	88°23.608′

(l) *McGrail Bank HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the HAPC, which is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (l)

Point	North lat.	West long.
A	27°59.100′	92°37.320′
B	27°59.100′	92°32.290′
C	27°55.925′	92°32.290′
D	27°55.925′	92°37.320′
A	27°59.100′	92°37.320′

(m) *AT 047 HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap and bottom anchoring by fishing vessels are prohibited year-round in the HAPC, which is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (m)

Point	North lat.	West long.
A	27°54.426′	89°49.404′
B	27°54.486′	89°46.464′
C	27°51.874′	89°46.397′
D	27°51.814′	89°49.336′
A	27°54.426′	89°49.404′

(n) *AT 357 HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the HAPC, which is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (n)

Point	North lat.	West long.
A	27°36.259′	89°43.068′
B	27°36.315′	89°40.136′
C	27°33.703′	89°40.073′
D	27°33.646′	89°43.004′
A	27°36.259′	89°43.068′

(o) *Green Canyon 852 HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the HAPC, which is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (o)

Point	North lat.	West long.
A	27°08.354′	91°08.929′
B	27°05.740′	91°08.963′
C	27°05.762′	91°10.610′
D	27°08.376′	91°10.567′
A	27°08.354′	91°08.929′

(p) *West Flower Garden Bank HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the HAPC, which is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (p)

Point	North lat.	West long.
A	27°55.380′	93°53.160′
B	27°55.380′	93°46.767′
C	27°49.050′	93°46.767′
D	27°49.050′	93°53.160′
A	27°55.380′	93°53.160′

(q) *East Flower Garden Bank HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the HAPC, which is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (q)

Point	North lat.	West long.
A	27°59.240′	93°38.970′
B	27°59.240′	93°34.058′
C	27°52.608′	93°34.058′
D	27°52.608′	93°38.970′
A	27°59.240′	93°38.970′

(r) *Stetson Bank HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the HAPC, which is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (r)

Point	North lat.	West long.
A	28°10.638′	94°18.608′
B	28°10.638′	94°17.105′
C	28°09.310′	94°17.105′
D	28°09.310′	94°18.608′
A	28°10.638′	94°18.608′

(s) *Harte Bank HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the HAPC, which is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (s)

Point	North lat.	West long.
A	26°40.826′	96°36.590′
B	26°40.789′	96°32.220′
C	26°37.992′	96°32.308′
D	26°38.043′	96°36.636′
A	26°40.826′	96°36.590′

(t) *Southern Bank HAPC.* Deployment of a bottom longline, bottom trawl, buoy gear, dredge, pot, or trap, and bottom anchoring by fishing vessels are prohibited year-round in the HAPC, which is bounded by rhumb lines connecting the following points in order:

TABLE 1 TO PARAGRAPH (t)

Point	North lat.	West long.
A	27°26.923′	96°31.902′
B	27°26.989′	96°30.881′
C	27°25.958′	96°31.134′
D	27°25.958′	96°31.892′
A	27°26.923′	96°31.902′

PART 635—ATLANTIC HIGHLY MIGRATORY FISHERIES

■ 3. The authority citation for part 635 continues to read as follows:

Authority: 16 U.S.C. 971 *et seq.;* 16 U.S.C. 1801 *et seq.*

■ 4. In § 635.21, revise paragraph (a)(3)(i) and add paragraph (a)(3)(v) to read as follows:

§ 635.21 Gear operation and deployment restrictions.

* * * * *

(a) * * *

(3) * * * (i) No person may fish for, catch, possess, or retain any Atlantic HMS or anchor a fishing vessel that has been issued a permit or is required to be permitted under this part, in the areas and seasons designated at § 622.34(a)(3) of this chapter.

* * * * *

(v) Within the areas of the Gulf coral HAPCs designated at § 622.74 of this chapter, no person may bottom anchor a fishing vessel or deploy fishing gear that may not be deployed pursuant to § 622.74 of this chapter. For purposes of this provision, fishing gear is deployed if any part of the gear is in contact with the water.

* * * * *

[FR Doc. 2019–24308 Filed 11–14–19; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 84, No. 221
Friday, November 15, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 12, 2019.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, Washington, DC; New Executive Office Building, 725 17th Street NW, Washington, DC 20503. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602.

Dates: Comments regarding these information collections are best assured of having their full effect if received by December 16, 2019. Copies of the submission(s) may be obtained by calling (202) 720–8681. An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service (NASS)

Title: Field Crops Production—County Estimates Survey—Row Crops—Substantive Change.

OMB Control Number: 0535–0002.

Summary of Collection: General authority for these data collection activities is granted under U.S. Code Title 7, Section 2204 which specifies that ''The Secretary of Agriculture shall procure and preserve all information concerning agriculture which he can obtain . . . by the collection of statistics . . .''. The primary objective of the National Agricultural Statistics Service (NASS) is to provide data users with timely and reliable agricultural production and economic statistics, as well as environmental and specialty agricultural related statistics. To accomplish this objective, NASS relies on the use of diverse surveys that show changes within the farming industry over time.

Numerous surveys included in the Agricultural Surveys Program (0535–0213) and the Field Crops Production docket (0535–0002) are used to set State and National estimates for numerous commodities. In order to publish data on a county level, much larger samples are needed. Within the Field Crops docket, are two surveys that collect supplemental data for the purpose of publishing county level data. Historically, the data collection costs for these two surveys has been partially funded through a cooperative agreement between NASS and the USDA Risk Management Agency (RMA). Due to program changes, RMA withdrew from this cooperative agreement this year. As a result, NASS is forced to reduce the County Estimates program. In the first step, NASS will reduce the number of commodities for which county level data will be made available. The commodities for which county level data will be discontinued are: Dry edible beans, flaxseed, hay (alfalfa and other), potatoes, sugarbeets, sugarcane, sunflower (non-oil and oil varieties) and tobacco. In addition, NASS will discontinue county estimates based on irrigated/non-irrigated practices. In the second step, in early 2020 NASS will evaluate the need for potentially more cost savings to the county estimate programs. If additional savings are needed, changes to small grain county estimates will be published in the **Federal Register**.

This substantive change resulted in an overall decrease in response burden of approximately 13,940 hours. The target sample size for enumerated questionnaires will be reduced by approximately 51,000.

Need and Use of the Information: County estimates for field crops are used by the Farm Service Agency (FSA) to carry out their legislative mandates. The primary use of the data is to determine average yields by county, used in determining participating farmers' compensation payments. The information is useful to the Natural Resources Conservation Service (NRCS) for administering programs. The information will also benefit the agricultural sector more generally by enabling the rental market for cropland to operate more competitively.

Description of Respondents: Farms sampled for the County Estimates—Row Crops.

Number of Respondents: 124,000.

Frequency of Responses: Reporting: Once.

Total Burden Hours: 33,894.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–24789 Filed 11–14–19; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Case No. 18–BIS–0002]

Order Relating to AW-Tronics LLC

In the Matter of:

AW-Tronics LLC, 7405 SW 79CT, Miami, FL 33143, et al.,

Respondents

The Bureau of Industry and Security, U.S. Department of Commerce (''BIS''), has notified AW-Tronics LLC, of Miami, Florida, (''AW-Tronics'') that it has initiated an administrative proceeding

against it pursuant to Section 766.3 of the Export Administration Regulations (the ''Regulations''),[1] through the issuance of a Charging Letter alleging that AW-Tronics, Ali Caby, Arash Caby, Marjan Caby, and Arrowtronic, LLC (''Arrowtronic'') (collectively, ''Respondents'') violated the Regulations as follows:

Charge 1 15 CFR 764.2(d)—Conspiracy

Beginning as early as in or about September 2013, and continuing through in or about March 2014, Respondents conspired and acted in concert with others, known and unknown, to bring about one or more acts that constitute a violation of the Regulations. The purpose and object of the conspiracy was to unlawfully export goods from the United States through transshipment points to Syria, including to Syrian Arab Airlines (''Syrian Air''), the flag carrier airline of Syria and a Specially Designated Global Terrorist (''SDGT''), and in doing so evade the prohibitions and licensing requirements of the Regulations and avoid detection by U.S. law enforcement.

Pursuant to Section 746.9 of the Regulations, a license is required for the export or reexport to Syria of all items subject to the Regulations, except food and medicine classified as EAR99. Furthermore, pursuant to Section 744.12 of the Regulations, a license is required to export or reexport items subject to the Regulations to SDGTs. Syrian Air was designated as an SDGT on May 16, 2013 (see 78 FR 32304, May 29, 2013), under authority granted to the Department of the Treasury by Executive Order 13,224, and was at all times pertinent hereto (and remains) listed as an SDGT.

At all pertinent times, AW-Tronics and Arrowtronic were active limited liability companies incorporated in the State of Florida. Documentary evidence and email correspondence shows that AW-Tronics personnel represented to various transaction parties that AW-Tronics and Arrowtronic (collectively, ''AW-Tronics/Arrowtronic'') were the same company. Arash Caby was listed on Florida corporate records as a Managing Member of AW-Tronics at the time of the violations. From January 2014 until its most recent annual report in January 2017, Ali Caby was listed on Florida corporate records as the registered agent of AW-Tronics. AW-Tronics/Arrowtronic has maintained offices in Miami, Florida and Sofia, Bulgaria, as well as other locations.

As part of the conspiracy, the co-conspirators used electronic mail (email) and other forms of communication to communicate with each other between the United States, Bulgaria, United Arab Emirates (UAE), and Syria. Under their scheme, co-conspirators would purchase from U.S. suppliers or vendors items subject to the Regulations for export to Syrian Air in Syria, including aircraft parts and equipment, and would provide materially false or misleading documents and information to conceal the illegal exports. In furtherance of the conspiracy, they also would arrange for payment for the illegal exports to be made using third-party companies to transfer payments between the co-conspirators. Overall, between in or about September 2013 and in or about March 2014, Respondents engaged in multiple transactions with Syrian Air involving the export of aircraft parts and equipment subject to the Regulations from the Miami office of AW-Tronics/Arrowtronic to Syrian Air's transshipment point in Dubai, United Arab Emirates. These items were actually intended for, and some or all were ultimately delivered to, Syrian Air in Syria.

During the conspiracy, Ali Caby managed the Bulgaria office of AW-Tronics/Arrowtronic, while Arash Caby managed its Miami office, and Marjan Caby was its internal auditor. In furtherance of the conspiracy, each of these respondents exchanged numerous emails with other AW-Tronics/Arrowtronic employees authorizing or otherwise discussing the above-described exports to Syrian Air. These email communications included, for example, instructions that were designed to prevent U.S. law enforcement from detecting the unlawful exports to Syria and to allow them to continue by changing the routing of exports from AW-Tronics/Arrowtronic's Miami, Florida office. In March 2014, United States Customs and Border Protection seized a shipment of micro switches that, according to Electronic Export Information (EEI) filed in the Automated Export System, was destined for Syrian Air in the UAE, when, in fact, the ultimate destination was Syria. On March 5, 2014, Marjan Caby sent an email to AW-Tronics/Arrowtronic logistics employees, copying Alex Caby, that explained, ''We will . . . have packages stopped by the US Customs and Border Control [and] have a case file like this for the same client[,]'' and provided instructions stating, ''NOTHING WILL BE SHIPPED TO CLIENTS IN THE MIDDLE EAST FROM THE USA OFFICE. WE HAVE TO SEND TO BG [Bulgaria] THEN TO CLIENT.'' (Emphasis in original). ''SYRIA'' was specifically listed as one country for which Respondents would use Bulgaria as a transshipment point. (Same).

In so doing, Ali Caby, a/k/a Alex Caby, Arash Caby, a/k/a ''Axel'' Caby, Marjan Caby, AW-Tronics, LLC, and Arrowtronic, LLC violated Section 764.2(d) of the Regulations, for which they are jointly and severally liable.

Whereas, BIS and AW-Tronics have entered into a Settlement Agreement pursuant to Section 766.18(b) of the Regulations, whereby they agreed to settle this matter in accordance with the terms and conditions set forth therein; and

Whereas, I have approved of the terms of the Settlement Agreement;

It is therefore ordered:

First, for the period of six (6) years from the date of this Order AW-Tronics LLC, with a last known address of 7405 SW 79CT, Miami, FL 33143, and when acting for or on its behalf, its successors, assigns, director, officers, representatives, agents, or employees (hereinafter collectively referred to as the ''Denied Person''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported to or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other

[1] The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. 4601–4623 (Supp. III 2015) (''the EAA''), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which was extended by successive Presidential Notices, continued the Regulations in full force and effect under the International Emergency Economic Powers Act, 50 U.S.C. 1701, *et seq.* (2012) (''IEEPA''). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2018). The charged violation occurred in 2013–2014. The Regulations governing the violation at issue are found in the 2013–2014 versions of the Code of Federal Regulations (15 CFR parts 730–774 (2013–2014)). The 2019 Regulations set forth the procedures that apply to this matter.

support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States, or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, any licenses issued under the Regulations in which AW-Tronics has an interest as of the date of this Order shall be revoked by BIS.

Fourth, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any person, firm, corporation, or business organization related to the Denied Person by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be made subject to the provisions of this Order.

Fifth, AW-Tronics shall not take any action or make or permit to be made any public statement, directly or indirectly, denying the allegations in the Charging Letter or this Order.

Sixth, the Charging Letter, the Settlement Agreement, and this Order shall be made available to the public.

Seventh, this Order shall be served on AW-Tronics and shall be published in the **Federal Register**.

This Order, which constitutes the final agency action in this matter related to AW-Tronics, is effective immediately.

Dated: October 30, 2019.

Douglas R. Hassebrock,

Director, Office of Export Enforcement, performing the non-exclusive functions and duties of the Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2019–24824 Filed 11–14–19; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–817]

Certain Oil Country Tubular Goods From the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that certain oil country tubular goods (OCTG) from the Socialist Republic of Vietnam (Vietnam) are being sold in the United States at less than normal value (NV) during the period of review (POR) September 1, 2017 through October 31, 2018. Interested parties are invited to comment on these preliminary results.

DATES: Applicable November 15, 2019.

FOR FURTHER INFORMATION CONTACT: Fred Baker, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2924.

SUPPLEMENTARY INFORMATION:

Background

On November 15, 2018, Commerce initiated an administrative review of the antidumping order on OCTG from Vietnam.[1] The review covers SeAH Steel VINA Corporation (SSV) and its U.S. affiliate Pusan Pipe America, Inc. (PPA).[2] Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the resumption of operations on January 29, 2019.[3] Commerce extended the deadline for the preliminary results until November 8, 2019.[4]

For a full description of events that have occurred since the *Initiation Notice, see* the Preliminary Decision Memorandum.[5] A list of topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The merchandise covered by the order is certain OCTG. The merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.10.10, 7304.29.10.20, 7304.29.10.30, 7304.29.10.40, 7304.29.10.50, 7304.29.10.60, 7304.29.10.80, 7304.29.20.10, 7304.29.20.20, 7304.29.20.30, 7304.29.20.40, 7304.29.20.50, 7304.29.20.60, 7304.29.20.80, 7304.29.31.10, 7304.29.31.20, 7304.29.31.30, 7304.29.31.40, 7304.29.31.50, 7304.29.31.60, 7304.29.31.80, 7304.29.41.10, 7304.29.41.20, 7304.29.41.30, 7304.29.41.40, 7304.29.41.50, 7304.29.41.60, 7304.29.41.80, 7304.29.50.15, 7304.29.50.30, 7304.29.50.45, 7304.29.50.60, 7304.29.50.75, 7304.29.61.15, 7304.29.61.30, 7304.29.61.45, 7304.29.61.60, 7304.29.61.75, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.29.10.30, 7306.29.10.90, 7306.29.20.00, 7306.29.31.00, 7306.29.41.00, 7306.29.60.10, 7306.29.60.50, 7306.29.81.10, and 7306.29.81.50.

The merchandise subject to the order may also enter under the following HTSUS item numbers: 7304.39.00.24, 7304.39.00.28, 7304.39.00.32, 7304.39.00.36, 7304.39.00.40,

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 57411 (November 15, 2018) (*Initiation Notice*).

[2] PPA is the importer of record for all of SSV's shipments of subject merchandise to the United States during the POR. *See* SSV December 19, 2018 Section A Questionnaire Response at 1.

[3] *See* Memorandum, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[4] *See* Memoranda, ''Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review,'' dated July 2, 2019; and ''Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review,'' dated October 9, 2019.

[5] *See* Memorandum, ''Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

7304.39.00.44, 7304.39.00.48, 7304.39.00.52, 7304.39.00.56, 7304.39.00.62, 7304.39.00.68, 7304.39.00.72, 7304.39.00.76, 7304.39.00.80, 7304.59.60.00, 7304.59.80.15, 7304.59.80.20, 7304.59.80.25, 7304.59.80.30, 7304.59.80.35, 7304.59.80.40, 7304.59.80.45, 7304.59.80.50, 7304.59.80.55, 7304.59.80.60, 7304.59.80.65, 7304.59.80.70, 7304.59.80.80, 7305.31.40.00, 7305.31.60.90, 7306.30.50.55, 7306.30.50.90, 7306.50.50.50, and 7306.50.50.70.

While the HTSUS subheadings above are provided for convenience and customs purposes, the written description is dispositive. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.

Methodology

Commerce conducted this review in accordance with sections 751(a)(1)(B) and 751(a)(2)(A) of the Tariff Act of 1930, as amended (the Act). Constructed export prices have been calculated in accordance with section 772(b) of the Act. Because Vietnam is a non-market economy (NME) within the meaning of section 771(18) of the Act, NV has been calculated in accordance with section 773(c) of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Application of Separate Rates in NME Proceedings

In the *Initiation Notice,* Commerce notified parties of the application process by which exporters may obtain separate rate status in an NME proceeding.[6] It is Commerce's policy to assign all exporters of the merchandise subject to review in NME countries a single rate unless an exporter can affirmatively demonstrate an absence of government control, both in law (*de jure*) and in fact (*de facto*), with respect to exports. To establish whether a company is sufficiently independent to be entitled to a separate, company-specific rate, Commerce analyzes each exporting entity in an NME country under the test established in *Sparklers,*[7] as further developed by *Silicon Carbide.*[8] However, if Commerce determines that a company is wholly foreign-owned, then an analysis of the *de jure* and *de facto* criteria is not necessary to determine whether it is independent from government control.[9]

Vietnam-Wide Entity

Commerce's policy regarding conditional review of the Vietnam-wide entity applies to this administrative review.[10] Under this policy, the Vietnam-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the Vietnam-wide entity in this review, the entity is not under review and the entity's rate (*i.e.,* 111.47 percent) [11] is not subject to change.

Preliminary Results of Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the period September 1, 2017 through August 31, 2018:

Exporter	Weighted-average margin (percent)
SeAH Steel VINA Corporation/Pusan Pipe America, Inc	1.78

Disclosure, Public Comment and Opportunity To Request a Hearing

Commerce will disclose the calculations used in our analysis to parties in this review within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs within 30 days after the date of publication of these preliminary results of review in the **Federal Register**.[12] Rebuttals to case briefs, which must be limited to issues raised in the case briefs, may be filed within five days after the time limit for filing case briefs.[13] Parties who submit arguments are requested to submit with the argument: (a) A statement of the issue, (b) a brief summary of the argument, and (c) a table of authorities.[14] Parties submitting briefs should do so pursuant to Commerce's electronic filing system, ACCESS.[15]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance within 30 days of the date of publication of this notice. Requests should contain the party's name, address and telephone number, the number of participants, whether any participant is a foreign national and a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a date and time to be determined.[16] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act, unless extended.

Assessment Rates

Upon issuance of the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[17] Commerce intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review.

For assessment purposes, Commerce applied the assessment rate calculation method adopted in the *Antidumping Final Modification.*[18] For any individually examined respondent whose weighted average dumping margin is above *de minimis* (*i.e.,* 0.50 percent) in the final results of this review, Commerce will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's

[6] *See Initiation Notice.*

[7] *See Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991) (*Sparklers*).

[8] *See Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994) (*Silicon Carbide*).

[9] *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles from the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

[10] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[11] *See Certain Oil Country Tubular Goods From the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 53691, 53694 (September 10, 2014).

[12] *See* 19 CFR 351.309(c)(1)(ii).

[13] *See* 19 CFR 351.309(d)(1)–(2); *see also* 19 CFR 351.303 (for general filing requirements).

[14] *See* 19 CFR 351.309(c)(2), (d)(2).

[15] *See* 19 CFR 351.303 (for general filing requirements).

[16] *See* 19 CFR 351.310(d).

[17] *See* 19 CFR 351.212(b).

[18] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012) (*Antidumping Final Modification*), in the manner described in more detail in the Preliminary Decision Memorandum.

examined sales to the total entered value of sales, in accordance with 19 CFR 351.212(b)(1). Where an importer- (or customer-) specific *ad valorem* rate is greater than *de minimis,* Commerce will instruct CBP to collect the appropriate duties at the time of liquidation.[19] Where either a respondent's weighted average dumping margin is zero or *de minimis,* or an importer- (or customer-) specific *ad valorem* is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[20]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise from Vietnam entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) For the companies listed above that have a separate rate, the cash deposit rate will be that established in the final results of this review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously examined Vietnamese and non-Vietnamese exporters not listed above that at the time of entry are eligible for a separate rate based on a prior completed segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific cash deposit rate; (3) for all Vietnamese exporters of subject merchandise that have not been found to be entitled to a separate rate at the time of entry, the cash deposit rate will be that for the Vietnamese-wide entity; and (4) for all non-Vietnamese exporters of subject merchandise that at the time of entry are not eligible for a separate rate, the cash deposit rate will be the rate applicable to the Vietnamese exporter that supplied that non-Vietnamese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: November 7, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Methodology
V. Duty Absorption
VI. Currency Conversion
VII. Recommendation

[FR Doc. 2019–24764 Filed 11–14–19; 8:45 am]

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[19] *See* 19 CFR 351.212(b)(1).

[20] *See* 19 CFR 351.106(c)(2).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–840]

Certain Frozen Warmwater Shrimp From India: Rescission of Antidumping Duty Administrative Review; 2018–2019, in Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On May 2, 2019, the Department of Commerce (Commerce) initiated an administrative review on frozen warmwater shrimp from India for the period February 1, 2018, through January 31, 2019, for 254 companies. Because all interested parties timely withdrew their requests for administrative review for certain companies, we are rescinding this administrative review with respect to those companies. For a list of the companies for which we are rescinding this review, *see* Appendix I to this notice. For a list of the companies for which the review is continuing, *see* Appendix II to this notice.

DATES: Applicable November 15, 2019.

FOR FURTHER INFORMATION CONTACT: Manuel Rey or Brittany Bauer, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5518 or (202) 482–3860.

SUPPLEMENTARY INFORMATION:

Background

On February 8, 2019, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on frozen warmwater shrimp from India for the period February 1, 2018, through January 31, 2019.[1] In February 2019, Commerce received timely requests, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), to conduct an administrative review of this antidumping duty order from the Ad Hoc Shrimp Trade Action Committee (the petitioner), the American Shrimp Processors Association (ASPA), and certain individual companies. Based upon these requests, on May 2, 2019, in accordance with section 751(a) of the Act, Commerce published in the **Federal Register** a notice of initiation listing 253 companies for which Commerce received timely requests for review.[2]

In July 2019, all interested parties timely withdrew their requests for an administrative review of certain companies.[3] These companies are listed in Appendix I.

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 2816 (February 8, 2019).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 18777 (May 2, 2019) (*Initiation Notice*).

[3] *See* Magnum Sea Foods Limited (MSL) and Magnum Estates Limited (MEL) (collectively, Magnum) Letter, ''*Magnum Withdrawal of Review Request for Administrative Review* of the Antidumping Duty Order on Certain Frozen Warmwater Shrimp from India,'' dated July 26, 2019; West Coast Frozen Foods Private Limited (West Coast) Letter, ''*Frozen Warmwater Shrimp from India—Withdrawal of Request for Antidumping Duty Admin Review of West Coast Frozen Foods Private Limited,*'' dated July 30, 2019; Jafadeesh Marine Exports' Letter, ''Certain Frozen Warmwater Shrimp from India: Withdrawal of Request for 14th Administrative Review covering the Period from 01st February 2018 to 31st January 2019,'' dated July 30, 2019; Mangala Marine Exim India Private Limited Letter, ''Certain Frozen Warmwater Shrimp from India: Withdrawal of Request for 14th Administrative Review covering the Period from 01st February 2018 to 31st January 2019,'' dated July 29, 2019; Liberty Group comprised of Devi Marine Food Exports (P) Ltd., Universal Cold Storage (P) Ltd., Kader Exports (P) Ltd., Liberty Frozen Foods (P) Ltd., Premier Marine Products (P) Ltd., Kader Investment & Trading Company (P) Ltd., and Liberty Oil Mills Limited) (collectively Liberty Group), Devi Fisheries Group (comprised of Devi Fisheries Limited, Satya Seafoods Private Limited, Usha Seafoods, and Devi Aquatech Private Limited), and Falcon Marine Exports Limited (Falcon) Letter, ''*Certain Frozen Warmwater Shrimp from India:* Withdrawal of Requests for Administrative Review for Liberty Group, Falcon and Devi Fisheries Group (2/01/18–1/31/19),'' dated July 30, 2019; twenty-five (25) Indian producers and/or exporters Letter, ''*Certain Frozen Warmwater Shrimp from India:* Withdrawal of Requests for Administrative Review for 25 Indian Producers/Exporters (02/01/18–01/31/19),'' dated

Partial Rescission

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. As noted above, certain parties withdrew their requests for review by the 90-day deadline. Accordingly, we are rescinding this administrative review with respect to the companies listed in Appendix I.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

July 30, 2019; Ad Hoc Shrimp Trade Action Committee (AHSTAC) Letter, ''Certain Frozen Warmwater Shrimp from India: Domestic Producers' Partial Withdrawal of Review Requests,'' dated July 30 2019; and American Shrimp Processors Association (ASPA) Letter, ''Certain Frozen Warmwater Shrimp from India: American Shrimp Processors Association's Partial Withdrawal of Review Requests,'' dated July 30, 2019.

Notification to Interested Parties

This notice is issued and published in accordance with section 751(a)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: November 8, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

Akshay Food Impex Private Limited
Alashore Marine Exports (P) Ltd.
Alpha Marine
Ananda Aqua Applications/Ananda Aqua Exports (P) Limited/Ananda Foods [4]
Ananda Enterprises (India) Private Limited
Anjaneya Seafoods
Apex Frozen Foods Private Limited [5]
Aquatica Frozen Foods Global Pvt. Ltd.
Arya Sea Foods Private Limited
Asvini Exports
Asvini Fisheries Ltd/Asvini Fisheries Private Ltd [6]
Avanti Frozen Foods Private Limited [7]
Bluepark Seafoods Pvt. Ltd.
BMR Exports
BMR Industries Private Limited
C.P. Aquaculture (India) Pvt. Ltd.
Calcutta Seafoods Pvt. Ltd./Bay Seafood Pvt. Ltd./Elque & Co.[8]
Castlerock Fisheries Ltd.
Choice Trading Corporation Pvt. Ltd.
Coastal Aqua
Coastal Aqua Private Limited [9]
Coastal Corporation Ltd.
Devi Fisheries Limited/Satya Seafoods Private Limited/Usha Seafoods/Devi Aquatech Private Limited [10]
Devi Marine Food Exports Private Ltd/Kader Exports Private Limited/Kader Investment and Trading Company Private Limited/Liberty Frozen Foods Pvt. Ltd./Liberty Oil Mills Ltd/Premier Marine Products Private Limited/Universal Cold Storage Private Limited [11]
Diamond Seafoods Exports/Edhayam Frozen Foods Pvt. Ltd/Kadalkanny Frozen Foods/Theva & Company [12]
Falcon Marine Exports Limited/KR Enterprises [13]
Geo Seafoods
Growel Processors Private Limited
IFB Agro Industries Limited
ITC Limited, International Business
ITC Ltd.
Jagadeesh Marine Exports
Jayalakshmi Sea Foods Pvt. Ltd.
K V Marine Exports
Kalyan Aqua & Marine Exp. India Pvt. Ltd.
KNC Agro Pvt. Ltd.
Magnum Sea Foods Limited/Magnum Estates Limited [14]
Mangala Marine Exim India Pvt. Ltd.
Mangala Seafoods
Milesh Marine Exports Private Limited
Monsun Foods Pvt. Ltd.
Munnangi Seafoods (Pvt) Ltd.
Naga Hanuman Fish Packers
Neeli Aqua Private Limited
Nekkanti Sea Foods Limited
Nezami Rekha Sea Foods Private Limited
Nila Sea Foods Exports

[4] In past reviews, Commerce has treated these companies as a single entity. *See, e.g., Certain Frozen Warmwater Shrimp from India: Final Results of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 32835 (July 16, 2018) (*2016–2017 AR Final*). Absent information to the contrary, we continue to treat these companies as a single entity for purposes of this administrative review.

[5] On December 11, 2012, Apex Frozen Foods Private Limited was found to be the successor-in-interest to Apex Exports. *See Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 73619 (December 11, 2012). Therefore, we did not initiate a separate administrative review with respect to Apex Exports.

[6] In past reviews, Commerce has treated these companies as a single entity. *See, e.g., 2016–2017 AR Final.* Absent information to the contrary, we continue to treat these companies as a single entity for purposes of this administrative review.

[7] On December 15, 2016, Avanti Frozen Foods Private Limited was found to be the successor-in-interest to Avanti Feeds Limited. *See Certain Frozen Warmwater Shrimp from India: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 81 FR 90774 (December 15, 2016). Therefore, we did not initiate a separate administrative review with respect to Avanti Feeds Limited.

[8] In the 2017–2018 administrative review of this order, Commerce preliminarily determined it was appropriate to treat the following companies as a single entity: Calcutta Seafoods Pvt. Ltd., Bay Seafood Pvt. Ltd., and Elque & Co (Elque). *See Certain Frozen Warmwater Shrimp from India: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018,* 84 FR 16843 (April 23, 2019) (*2017–2018 AR Prelim*) and accompanying Issues and Decision Memorandum at 3.

[9] On October 3, 2018, Coastal Aqua Private Limited was found to be the successor-in-interest to Coastal Aqua. *See Certain Frozen Warmwater Shrimp from India: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 83 FR 49909 (October 3, 2018). Because the effective date of this determination is during the current POR, we included both exports from Coastal Aqua and Coastal Aqua Private Limited in this review.

[10] In past reviews, Commerce has treated these companies as a single entity. *See, e.g., 2016–2017 AR Final.* Absent information to the contrary, we continue to treat these companies as a single entity for purposes of this administrative review.

[11] In past reviews, Commerce has treated these companies as a single entity. *Id.* Absent information to the contrary, we continue to treat these companies as a single entity for purposes of this administrative review. Additionally, on December 2, 2014, Premier Marine Products Private Limited was found to be the successor-in-interest to Premier Marine Products. *See Notice of Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 79 FR 71384 (December 2, 2014).

[12] In past reviews, Commerce has treated these companies as a single entity. *See, e.g., 2016–2017 AR Final.* Absent information to the contrary, we continue to treat these companies as a single entity for purposes of this administrative review.

[13] In past reviews, Commerce has treated these companies as a single entity. *Id.* Absent information to the contrary, we continue to treat these companies as a single entity for purposes of this administrative review.

[14] In the 2017–2018 administrative review of this order, Commerce preliminarily determined it was appropriate to treat Magnum Sea Foods Limited and Magnum Estates Limited as a single entity. *See 2017–2018 AR Prelim,* 84 FR at 16845 and accompanying Issues and Decision Memorandum at 3.

Nila Sea Foods Pvt. Ltd.
Pasupati Aquatics Private Limited
Penver Products (P) Ltd.
Ram's Assorted Cold Storage Ltd.
Royale Marine Impex Private Limited
SA Exports
Sagar Grandhi Exports Pvt. Ltd.
Sai Marine Exports Pvt. Ltd.
Sai Sea Foods
Sandhya Aqua Exports
Sandhya Aqua Exports Pvt. Ltd.
Sandhya Marines Limited
Sharat Industries Ltd.
Shree Datt Aquaculture Farms Pvt. Ltd.
Southern Tropical Foods Pvt. Ltd.
Sprint Exports Pvt. Ltd.
Sunrise Aqua Food Exports [15]
Suryamitra Exim (P) Ltd.
V V Marine Products
Vasista Marine
Veerabhadra Exports Private Limited
Wellcome Fisheries Limited
West Coast Fine Foods (India) Private Limited
West Coast Frozen Foods Private Limited

Appendix II

Abad Fisheries
Albys Agro Private Limited
Allana Frozen Foods Pvt. Ltd.
Allanasons Ltd.
Amarsagar Seafoods Private Limited
AMI Enterprises
Amulya Seafoods
Anatha Seafoods Private Limited
Angelique International Ltd.
Ayshwarya Seafood Private Limited
B R Traders
Baby Marine Eastern Exports
Baby Marine Exports
Baby Marine International
Baby Marine Sarass
Baby Marine Ventures
Balasore Marine Exports Private Limited
Bell Exim Private Limited (Bell Foods (Marine Division))
Bhatsons Aquatic Products
Bhavani Seafoods
Bijaya Marine Products
Blue Fin Frozen Foods Pvt. Ltd.
Blue Water Foods & Exports P. Ltd.
B-One Business House Pvt. Ltd.
Britto Seafood Exports Pvt Ltd.
Canaan Marine Products
Capithan Exporting Co.
Cargomar Private Limited
Chakri Fisheries Private Limited
Chemmeens (Regd)
Cherukattu Industries (Marine Div)
Cochin Frozen Food Exports Pvt. Ltd.
Continental Fisheries India Private Limited
Coreline Exports
Corlim Marine Exports Pvt. Ltd.
Crystal Sea Foods Private Limited
D2 D Logistics Private Limited
Damco India Private
Delsea Exports Pvt. Ltd.
Devi Sea Foods Limited [16]
Entel Food Products Private Limited
Esmario Export Enterprises
Everblue Sea Foods Private Limited
Exporter Coreline Exports
Febin Marine Foods
Five Star Marine Exports Private Limited
Forstar Frozen Foods Pvt. Ltd.
Fouress Food Products Private Limited
Frontline Exports Pvt. Ltd.
G A Randerian Ltd.
Gadre Marine Exports
Galaxy Maritech Exports P. Ltd.
Geo Aquatic Products (P) Ltd.
Goodwill Enterprises
Grandtrust Overseas (P) Ltd.
Green House Agro Products
GVR Exports Pvt. Ltd.
Hari Marine Private Limited
Haripriya Marine Export Pvt. Ltd.
Harmony Spices Pvt. Ltd.
HIC ABF Special Foods Pvt. Ltd.
Hindustan Lever, Ltd.
Hiravata Ice & Cold Storage
Hiravati Exports Pvt. Ltd.
Hiravati International Pvt. Ltd. (located at APM-Mafco Yard, Sector-18, Vashi, Navi, Mumbai-400 705, India)
Hiravati International Pvt. Ltd. (located at Jawar Naka, Porbandar, Gujarat, 360 575, India)
Hiravati Marine Products Private Limited
HN Indigos Private Limited
Hyson Logistics and Marine Exports Private Limited
Indian Aquatic Products
Indo Aquatics
Indo Fisheries
Indo French Shellfish Company Private Limited
Innovative Foods Limited
International Freezefish Exports
Interseas
Jinny Marine Traders
Jiya Packagings
Kalyanee Marine
Kanch Ghar
Karunya Marine Exports Private Limited
Kaushalya Aqua Marine Product Exports Pvt. Ltd.
Kay Kay Exports
Kings Marine Products
Koluthara Exports Ltd.
Landauer Ltd.
Libran Cold Storages (P) Ltd.
Magnum Export
Malabar Arabian Fisheries
Malnad Exports Pvt. Ltd.
Mangala Sea Products
Marine Harvest India
Meenaxi Fisheries Pvt. Ltd.
Megaa Moda Pvt. Ltd.
Milsha Agro Exports Private Limited
Mourya Aquex Pvt. Ltd.
MTR Foods
N.C. John & Sons (P) Ltd.
Naik Frozen Foods
Naik Oceanic Exports Pvt. Ltd./Rafiq Naik Exports Pvt. Ltd.[17]
Naik Seafoods Ltd.
Nekkanti Mega Food Park Private Limited
Nine Up Frozen Foods
Nutrient Marine Foods Limited
Oceanic Edibles International Limited
Paragon Sea Foods Pvt. Ltd.
Paramount Seafoods
Parayil Food Products Pvt., Ltd.
Pesca Marine Products Pvt., Ltd.
Pijikay International Exports P Ltd.
Pisces Seafoods International
Pravesh Seafood Private Limited
Premier Exports International
Premier Marine Foods
Premier Seafoods Exim (P) Ltd.
R F Exports
R V R Marine Products Limited
Raa Systems Pvt. Ltd.
Raju Exports
Raunaq Ice & Cold Storage
Raysons Aquatics Pvt. Ltd.
Razban Seafoods Ltd.
RBT Exports
RDR Exports
RF Exports Private Limited
Riviera Exports Pvt. Ltd.
Rohi Marine Private Ltd.
Royal Imports and Exports
RSA Marines
S & S Seafoods
S Chanchala Combines
Safa Enterprises
Sagar Foods
Sagar Samrat Seafoods
Sagravihar Fisheries Pvt. Ltd.
Salvam Exports (P) Ltd.
Samaki Exports Private Limited
Sanchita Marine Products P Limited
Santhi Fisheries & Exports Ltd.
Sarveshwari Exp.
Sea Foods Private Limited
Sea Gold Overseas Pvt. Ltd.
Selvam Exports Private Limited
Sharma Industries
Shimpo Exports Private Limited
Shimpo Seafoods Private Limited
Shiva Frozen Food Exp. Pvt. Ltd.
Shroff Processed Food & Cold Storage P Ltd.
Silver Seafood
Sita Marine Exports
Sowmya Agri Marine Exports
Sri Sakkthi Cold Storage
Sri Venkata Padmavathi Marine Foods Pvt. Ltd.
Srikanth International [18]
SSF Ltd.
Star Agro Marine Exports Private Limited
Star Organic Foods Incorporated
Star Organic Foods Private Limited

[15] On September 27, 2019, Commerce issued the final results of a changed circumstances review and determined that Sunrise Seafoods India Private Limited is the successor in interest to Sunrise Aqua Food Exports. *See Certain Frozen Warmwater Shrimp from India: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 84 FR 51114 (September 27, 2019).

[16] Shrimp produced and exported by Devi Sea Foods Limited (Devi) was excluded from the order effective February 1, 2009. *See Certain Frozen Warmwater Shrimp from India: Final Results of the Antidumping Duty Administrative Review, Partial Rescission of Review, and Notice of Revocation of Order in Part,* 75 FR 41813, 41814 (July 19, 2010). Accordingly, we initiated this administrative review with respect to Devi only for shrimp produced in India where Devi acted as either the manufacturer or exporter (but not both).

[17] In past reviews, Commerce has treated these companies as a single entity. *See, e.g., 2016–2017 AR Final.* Absent information to the contrary, we continue to treat these companies as a single entity for purposes of this administrative review.

[18] On August 27, 2010, Srikanth International was found to be the successor-in-interest to NGR Aqua International. *See Certain Warmwater Shrimp from India: Final Results of Antidumping Duty Changed Circumstances Review,* 75 FR 52718 (August 27, 2010). Therefore, we did not initiate a separate administrative review with respect to NGR Aqua International.

Stellar Marine Foods Private Limited
Sterling Foods
Sun Agro Exim
Sun-Bio Technology Ltd.
Supran Exim Private Limited
Suvarna Rekha Exports Private Limited
Suvarna Rekha Marine P Ltd.
TBR Exports Pvt Ltd.
Teekay Marine P. Ltd.
The Waterbase Limited
Triveni Fisheries P. Ltd.
U & Company Marine Exports
Ulka Sea Foods Private Limited
Uniroyal Marine Exports Ltd.
Unitriveni Overseas
V.S Exim Pvt Ltd.
Vasai Frozen Food Co.
Veejay Impex
Veronica Marine Exports Private Limited
Victoria Marine & Agro Exports Ltd.
Vinner Marine
Vitality Aquaculture Pvt. Ltd.
VRC Marine Foods LLP
Z A Sea Foods Pvt. Ltd.
Zeal Aqua Limited

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–051]

Certain Hardwood Plywood Products From the People's Republic of China: Partial Rescission of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is partially rescinding its administrative review of the antidumping duty order on certain hardwood plywood products (hardwood plywood) from the People's Republic of China (China) for the period June 23, 2017 through December 31, 2018.

DATES: Applicable November 15, 2019.

FOR FURTHER INFORMATION CONTACT: Nicolas Mayora or Kabir Archuletta, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3053 or (202) 482–2593, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 8, 2019, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty (AD) order on hardwood plywood from China for the period of review (POR) June 23, 2017, through December 31, 2018.[1] Pursuant to requests from interested parties, Commerce initiated an administrative review with respect to 58 companies in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[2] Subsequent to the initiation of the administrative review, several interested parties timely withdrew their request for 29 of these companies, as discussed below. No other party requested an administrative review of these companies.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication of the notice of initiation. The request for an administrative review of the following companies was withdrawn within 90 days of the date of publication of the *Initiation Notice:* Celtic Co., Ltd.;[3] Feixian Longteng Wood Co., Ltd.;[4] Golder International Trade Co., Ltd.;[5] Highland Industries–Hanlin.;[6] Huainan Mengping Import and Export Co., Ltd.;[7] Jiangsu Top Point International Co., Ltd.;[8] Jiaxing Gsun Imp. & Exp. Co., Ltd.;[9] Lianyungang Yuantai International Trade Co., Ltd. (Yuantai);[10] Linyi City Dongfang Jinxin Economic and Trade Co., Ltd. (a/k/a Linyi City Dongfang Jinxjin Economic and Trade Co., Ltd.;[11] Linyi Hengsheng Wood Industry Co., Ltd.;[12] Linyi Linhai Wood Co., Ltd.;[13] Linyi Mingzhu Wood Co., Ltd.;[14] Qingdao Good Faith Import and Export Co., Ltd.;[15] Shandong Dongfang Bayley Wood Co., Ltd.;[16] Shandong Jinluda International Trade Co., Ltd.;[17] Shandong Qishan International Trading Co., Ltd.;[18] Shandong Senmanqi Import & Export Co., Ltd., Ltd.;[19] Shandong Shengdi International Trading Co., Ltd.;[20] Suining Pengxiang Wood Co., Ltd.;[21] Sumec International Technology Co., Ltd.;[22] Suzhou Fengshuwan Import and Export Trade Co., Ltd. a/k/a Suzhou Fengshuwan I&E Trade Co., Ltd.;[23] Vietnam Finewood Company Limited.;[24] Win Faith Trading Limited.;[25] Xuzhou Andefu Wood Co., Ltd.;[26] Xuzhou DNT Commercial Co., Ltd.;[27] Xuzhou Longyuan Wood Industry Co., Ltd.;[28] XuZhou PinLin International Trade Co., Ltd.;[29] Xuzhou Shengping Imp and Exp Co., Ltd.;[30]

[1] *See Antidumping and Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Reviews,* 84 FR 2816 (February 8, 2019).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 12200 (April 1, 2019).

[3] *See* Shandong Dongfang Bayley Wood Co., Ltd (Bayley) *et al.* Letter, ''Hardwood Plywood Products from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated June 25, 2019 (Bayley Withdrawal Letter); s*ee also* Richmond International Forest Products LLC (RIFP) Letter, ''Administrative Review of the Antidumping and Countervailing Duty Order on Plywood Products from the People's Republic of China,'' dated June 21, 2019 (RIFP Withdrawal Letter); and Sierra Forest Products Inc. (SFP) Letter, ''Administrative Review of the Antidumping and Countervailing Duty Order on Plywood Products from the People's Republic of China: Withdrawal of Request for Review,'' dated June 21, 2019 (SFP Withdrawal Letter).

[4] *See* Bayley Withdrawal Letter.

[5] *Id.*

[6] *See* Morgan Truck Body LLC (Morgan) Letter, ''Certain Hardwood Plywood Products from China: Withdrawal of Request for Review,'' dated June 26, 2019.

[7] *See* Bayley Withdrawal Letter.

[8] *Id.*

[9] *Id.*

[10] *See* SFP Withdrawal Letter; *see also* Yuantai's Letter, ''Certain Hardwood Plywood Products from China: Withdrawal of Request for Administrative Review,'' dated July 1, 2019.

[11] *See* Canusa Wood Products Ltd. (Canusa) Letter, ''Administrative Review of the Antidumping and Countervailing Duty Order on Plywood Products from the People's Republic of China: Withdrawal of Request for Review,'' dated June 21, 2019 (Canusa Withdrawal Letter); *see also* Canusa's Letter, ''Administrative Review of the Antidumping Duty Order on Plywood Products from the People's Republic of China: Clarification of Withdrawal of Request for Review,'' dated November 6, 2019.

[12] *See* Bayley Withdrawal Letter.

[13] *See* Bayley Withdrawal Letter; *see also* Taraca Pacific Inc. (Taraca) Letter, ''Administrative Review of the Antidumping and Countervailing Duty Order on Plywood Products from the People's Republic of China: Withdrawal of Request for Review,'' dated June 28, 2019 (Taraca Withdrawal Letter).

[14] *See* Bayley Withdrawal Letter; *see also* RIFP Withdrawal Letter.

[15] *See* Bayley Withdrawal Letter.

[16] *Id.*

[17] *Id.*

[18] *See* Bayley Withdrawal Letter; *see also* Taraca Withdrawal Letter.

[19] *See* Bayley Withdrawal Letter; *see also* Shandong Senmanqi Import & Export Co., Ltd Letter, ''Hardwood Plywood Products from the People's Republic of China: Clarification of Senmanqi's Name,'' dated November 7, 2019.

[20] *Id.*

[21] *Id.*

[22] *See* Bayley Withdrawal Letter; *see also* RIFP Withdrawal Letter.

[23] *See* Concannon Corp. (Concannon) Letter, ''Administrative Review of the Antidumping and Countervailing Duty Order on Plywood Products from the People's Republic of China: Withdrawal of Request for Review,'' dated June 21, 2019 (Concannon Withdrawal Letter).

[24] *See* Vietnam Finewood Company Limited Letter, ''Hardwood Plywood Products from the Republic of China: Withdrawal of Request for Administrative Review,'' dated June 28, 2019.

[25] *See* SFP withdrawal Letter.

[26] *See* Bayley Withdrawal Letter.

[27] *Id.*

[28] *Id.*

[29] *See* Canusa Withdrawal Letter.

[30] *See* Bayley Withdrawal Letter.

Yishui Zelin Wood Made Co., Ltd.[31] All review requests were withdrawn for these 29 companies, as detailed above. As a result, pursuant to 19 CFR 351.213(d)(1), Commerce is rescinding the administrative review of the AD order on certain hardwood plywood products with respect to these 29 companies. The instant review will continue with respect to the remaining companies for which a review was initiated on.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. For the companies for which this review is rescinded, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse for consumption, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue appropriate assessment instruction to CBP 15 days after publication of this notice in the **Federal Register**, if appropriate.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of any antidumping or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of any antidumping or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction. This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

[31] *Id.*

Dated: November 8, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–24827 Filed 11–14–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Notice of Correction to the Final Results of the 2016–2017 Antidumping Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is correcting its notice of the final results of the fifth administrative review of the antidumping duty (AD) order on crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from the People's Republic of China (China). The period of review (POR) is December 1, 2016 through November 30, 2017.

DATES: Applicable November 15, 2019.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen, AD/CVD Operations, Office IV, Enforcement & Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2769.

SUPPLEMENTARY INFORMATION: On July 30, 2019, Commerce published the final results of the 2016–2017 administrative review of the AD order on solar cells from China in the **Federal Register**.[1] In the *Final Results,* we incorrectly included Zhejiang ERA Solar Technology Co., Ltd. (Zhejiang ERA) in the list of companies we were continuing to find had made no shipments of subject merchandise to the United States during the POR. However, in the *Preliminary Results* we stated the following:

> We found that . . . Zhejiang ERA Solar Technology Co., Ltd., which claimed no exports, sales or entries of subject merchandise during the POR did, in fact, sell subject merchandise to the United States during the POR. {This company did not file} a separate rate application or certification and thus {it has} not established {its} entitlement to a separate rate in this review.[2]

We based this preliminary finding on record evidence that Zhejiang ERA sold subject merchandise to the United States during the POR.[3] We provided Zhejiang ERA an opportunity to discuss the evidence at the time that we placed it on the record.[4] While Zhejiang ERA Solar Technology Co., Ltd. commented on the information, it provided no evidence contradicting the information that it had a shipment.[5] We also provided Zhejiang ERA with an opportunity to submit a case brief concerning our *Preliminary Results,* but Zhejiang ERA did not submit a case brief. Commerce did not intend to change our preliminary decision with respect to Zhejiang ERA's no shipment claim or our preliminary finding that this company was not eligible for a separate rate. We inadvertently erred when we included Zhejiang ERA in the list of companies that we found did not ship subject merchandise to the United States during the POR. Therefore, we are correcting the *Final Results* by clarifying that we have adopted our *Preliminary Results* with respect to Zhejiang ERA in the *Final Results.* Specifically, we are continuing to find that Zhejiang ERA did in fact have shipments of subject merchandise to the United States during the POR and that Zhejiang ERA is not eligible for separate rate status, and thus is part of the China-wide entity. As we noted in the *Final Results,* the China-wide entity rate is 238.95 percent.[6]

This correction to the final results and notice are issued and published in accordance with sections 751(a) and 777(i) of the Tariff Act of 1930, as amended.

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2016–2017,* 84 FR 36886 (July 30, 2019) (*Final Results*).

[2] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2016–2017,* 83 FR 67222, 67223 (December 28, 2018) (*Preliminary Results*).

[3] *Id.*

[4] *See* Memorandum, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Release of U.S. Customs and Border Protection Information Relating to No Shipment Claims Made in the 2014–2015 {sic} Administrative Review of Crystalline Silicon Photovoltaic Cells from the People's Republic of China,'' dated November 21, 2018.

[5] *See* Zhejiang ERA's Letter, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules from the People's Republic of China, Case No. A–570–979: Comments on Release of U.S. Customs and Border Protection Information Relating to No Shipment Claims,'' dated November 28, 2018.

[6] *See Final Results,* 84 FR at 36888.

Dated: November 1, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–24826 Filed 11–14–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV130]

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings of the North Pacific Fishery Management Council and its advisory committees.

SUMMARY: The North Pacific Fishery Management Council (Council) and its advisory committees will meet in December.

DATES: The meetings will be held Monday, December 2, 2019 through Tuesday, December 10, 2019. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES:

Meeting Address: The meeting will be held at the Anchorage Hilton Hotel, 500 W 3rd Ave., Anchorage, AK 99501.

Council Address: North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The Council will begin its plenary session at 8 a.m. in the Aleutian Room on Wednesday, December 4, 2019 continuing through Tuesday, December 10, 2019. The Council's Scientific and Statistical Committee (SSC) will begin at 8 a.m. in the King Salmon/Iliamna Room on Monday, December 2, 2019 and continue through Wednesday, December 4, 2019. The Council's Advisory Panel (AP) will begin at 8 a.m. in the Dillingham/Katmai Room on Tuesday, December 3, 2019 and continue through Saturday, December 7, 2019. The Community Engagement Committee will meet on Monday, December 2, 2019 in the Fireweed Room from 1 p.m. to 5 p.m. The Charter Halibut Management Committee will meet on Tuesday, December 3, 2019 in the Birch/Willow Room from 8 a.m. to 3 p.m. The Enforcement Committee will meet on Tuesday, December 3, 2019 in the Fireweed Room from 10:30 a.m. to 1 p.m.

Agenda

Monday, December 2, 2019 Through Tuesday, December 10, 2019

Council Plenary Session: The agenda for the Council's plenary session will include the following issues. The Council may take appropriate action on any of the issues identified.

1. Executive Director's Report
2. NMFS Management Report
3. NOAA General Counsel Report
4. NOAA Enforcement Report
5. ADF&G Report (including Biennial Halibut Subsistence report)
6. USCG Report
7. USFWS Report
8. IPHC Report
9. BSAI Groundfish Specifications
10. GOA Groundfish Specifications
11. 2020 Charter Halibut Management Measures for Areas 2C and 3A
12. BSAI Parallel Waters—Final Action
13. Crab Partial Deliveries—Final Action
14. St Matthew Blue King Crab Rebuilding Plan
15. Central Gulf of Alaska Rockfish Reauthorization
16. Non-Guided Halibut Rental Boat Registration
17. Halibut abundance-based management workplan
18. Sablefish Discards
19. Aleutian Islands Community Follow Up
20. Staff Tasking

The Advisory Panel will address Council agenda items 9 through 20, with the exception of item 17, which is Council only.

The SSC agenda will include the following issues:

1. BSAI Groundfish Specifications
2. GOA Groundfish Specifications
3. St. Matthew Blue King Crab Rebuilding Plan
4. Central GOA Rockfish Reauthorization
5. Comments on National Standard 1 Technical Guidance on ABC control rule provisions

In addition to providing ongoing scientific advice for fishery management decisions, the SSC functions as the Council's primary peer review panel for scientific information, as described by the Magnuson-Stevens Act section 302(g)(1)(e), and the National Standard 2 guidelines (78 FR 43066). The peer review process is also deemed to satisfy the requirements of the Information Quality Act, including the OMB Peer Review Bulletin guidelines.

The Community Engagement Committee will review existing Council engagement strategies and practices to develop recommendations to improve Council engagement with rural and Alaska Native communities. The Charter Halibut Management Committee will discuss 2020 Charter Halibut Measures for Areas 2C and 3A and the non-guided halibut rental boat registration analysis. The Enforcement Committee will discuss the non-guided halibut rental boat registration analysis, and other business.

The Agendas are subject to change, and the latest versions will be posted at *http://www.npfmc.org/*.

Public Comment

Public comment letters will be accepted and should be submitted either electronically at*: meetings.npfmc.org*or through the mail: North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501–2252. Deadline for comments is November 29, 2019, at 12 p.m.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Maria Davis at (907) 271–2809 at least 7 working days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 12, 2019.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2019–24787 Filed 11–14–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV132]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Committees.

DATES: The meetings will be held Monday, December 9, 2019, from 9 a.m. to 5:30 p.m.; Tuesday, December 10, 2019, from 9 a.m. to 5 p.m.; Wednesday,

December 11, 2019, from 9 a.m. to 5 p.m.; and, Thursday, December 12, 2019, from 9 a.m. to 1 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at the Westin Annapolis, 100 Westgate Circle, Annapolis, MD 21401; telephone: (410) 972–4300.

Council address: Mid-Atlantic Fishery Management Council, 800 N State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's website, *www.mafmc.org* also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Monday, December 9, 2019

Executive Committee (Closed Session)

Ricks E Savage Award

2020–24 Strategic Plan

Review public comments and approve 2020–2024 Strategic Plan

2020–24 Research Priorities

Review and approve research priorities document

Risk Policy Framework—Meeting #2

Review results of biological and economic management strategy evaluations and select preferred alternative(s)

Surfclam and Ocean Quahog Excessive Shares Amendment

Review public hearing comments and Committee recommendations and select preferred alternatives and take final action

Tuesday, December 10, 2019

Habitat Update

Update on NRHA Assessment, presentation on CCC Habitat Workshop and update of Projects of Interest in the Region

EAFM Summer Flounder Conceptual Model

Presentation of Oscar E. Sette Award (American Fisheries Society)

SSC Membership White Paper

Review and determine future SSC membership needs and expertise

Bluefish 2020 Recreational Specifications

Review recent fishery performance, Monitoring Committee, and Advisory Panel recommendations, adopt recommendation for 2020 federal waters recreational management measures

Bluefish Allocation and Rebuilding Amendment

Review and approve supplemental scoping document for additional scoping hearings

Summer Flounder 2020 Recreational Specifications

Review recent fishery performance, Monitoring Committee, and Advisory Panel recommendations, recommend Conservation Equivalency or coastwide management and associated measures for 2020

Wednesday, December 11, 2019

Scup 2020 Recreational Specifications

Review recent fishery performance, Monitoring Committee, and Advisory Panel recommendations, adopt recommendations for 2020 federal waters recreational management measures

Black Sea Bass 2020 Recreational Specifications

Review fishery performance, Monitoring Committee, and Advisory Panel recommendations, adopt recommendations for 2020 federal waters recreational management measures

Seized Commercial Catch and the Quota Monitoring/Accountability Process

Summer Flounder, Scup, and Black Sea Bass Commercial/Recreational Allocation Amendment

Review and approve draft scoping document

Black Sea Bass Commercial Allocation Addendum/Amendment

Discuss options for addressing potential impacts of coastwide quota management in federal waters on states

Commercial eVTR Omnibus Framework—Meeting #2

Select preferred alternatives and take final action

Thursday, December 12, 2019

2020 Implementation Plan

Review and approve 2020 Implementation Plan

Business Session

Committee Reports: SSC and Executive Committee; Executive Director's Report; Organization Reports; and, Liaison Reports

Continuing and New Business

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 12, 2019.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2019–24790 Filed 11–14–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Sunsetting of Raster Nautical Charts

AGENCY: Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice; request for comments.

SUMMARY: NOAA is undertaking a five-year program to end all raster and paper nautical chart production. Ultimately, production of all NOAA paper nautical charts, raster navigational charts (NOAA RNC®), and related products, such as BookletCharts™ will cease. NOAA is seeking feedback from chart users and companies that provide products and services based on NOAA raster and electronic navigational chart (NOAA ENC®) products. This information will shape the manner and timing in which

the product sunsetting process will proceed. More detailed information regarding this transition is available from *https://nauticalcharts.noaa.gov/publications/docs/raster-sunset.pdf.*

DATES: Comments are due by midnight, February 1, 2020.

ADDRESSES: Submit comments on the Sunsetting of Raster Nautical Charts through NOAA's ASSIST feedback tool at *https://nauticalcharts.noaa.gov/customer-service/assist,* or via mail to National Ocean Service, NOAA (NCS2), ATTN Sunset of Raster Charts, 1315 East-West Highway, Silver Spring, MD 20910–3282.

SUPPLEMENTARY INFORMATION: The Coast and Geodetic Survey Act of 1947 and the Hydrographic Services Improvement Act requires that NOAA compile and distribute nautical charts and other nautical publications. These statutes do not specify a particular format for chart products. NOAA and its predecessor agencies have produced paper nautical charts of the U.S. Coasts, its territorial waters, and the Great Lakes since the mid-1800s. NOAA has produced electronic navigational charts (ENCs) since 1993.

The International Maritime Organization now mandates that all large commercial vessels on international voyages use ENCs. In 2016, the USCG started allowing regulated commercial vessels on domestic voyages to use ENCs in lieu of paper charts. Recreational boaters are also increasingly using electronic chart displays.

Use of NOAA ENCs surpassed paper nautical charts in 2011. ENC sales increased 425% since 2008, while sales of paper charts are now half of 2008 levels. The current NOAA nautical chart product suites comprise 1,258 electronic navigational charts (NOAA ENC®) and 1,007 NOAA raster/paper nautical charts. NOAA has started a multi-year program to create a standard gridded layout and increase the scale of ENCs. This will increase the number of detailed NOAA ENCs to about 9,000.

NOAA is undertaking a five-year program to end all raster and paper nautical chart production. Ultimately, production of all NOAA paper nautical charts, raster navigational charts (NOAA RNC®), and related products, such as BookletCharts™ will cease.

NOAA is taking steps to provide a NOAA Custom Chart web-based application that will enable users to download and print raster chart backup files created from the most up-to-date ENC data. The NOAA Custom Chart prototype is available from *https://devgis.charttools.noaa.gov/pod.* These chart backup files will look somewhat different than traditional paper nautical charts, but will provide a similar functionality.

NOAA seeks comments from the public regarding the raster and paper chart product sunset transition and is particularly interested in:

- suggestions for improving the NOAA Custom Chart web application, and
- understanding other non-navigational uses for paper or raster nautical charts.

Richard Brennan,

Acting Director, Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2019–24807 Filed 11–14–19; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV131]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council, NEFMC) will hold a three-day meeting to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Tuesday, Wednesday, and Thursday, December 3, 4, and 5, 2019, beginning at 9 a.m. on December 3 and 8:30 a.m. on December 4 and 5.

ADDRESSES: The meeting will be held at the Hotel Viking, 1 Bellevue Avenue, Newport, RI 02840; telephone (401) 847–3300; online at *www.hotelviking.com.*

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone (978) 465–0492; *www.nefmc.org.*

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492, ext. 113.

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, December 3, 2019

After introductions and brief announcements, the meeting will begin with reports from the Council Chairman and Executive Director, NMFS's Regional Administrator for the Greater Atlantic Regional Fisheries Office (GARFO), liaisons from the Northeast Fisheries Science Center (NEFSC) and Mid-Atlantic Fishery Management Council, staff from the Atlantic States Marine Fisheries Commission (ASMFC), and representatives from NOAA General Counsel, NOAA's Office of Law Enforcement, and the U.S. Coast Guard. The Council then will receive a report on the 2019 annual meeting of the Northwest Atlantic Fisheries Organization (NAFO), followed by a report on the Northeast Trawl Advisory Panel's most recent meeting. Next, the Council will receive a NOAA Enforcement overview of the Carlos Rafael case, followed by a Coast Guard presentation on misreporting issues and their implications. Then, members of the public will have the opportunity to speak during an open comment period on issues that relate to Council business but are not included on the published agenda for this meeting. The Council asks the public to limit remarks to 3–5 minutes.

Following the lunch break, the Council will review Draft National Standard 1 Technical Guidance for Carry-over and Phase-in Provisions within Acceptable Biological Catch (ABC) control rules and approve Council comments on the draft. The Skate Committee Report will be up next. The Council will receive a progress report on Amendment 5 to the Northeast Skate Complex Fishery Management Plan (FMP), which proposes to establish a limited access program for the skate wing and/or skate bait fisheries. Then, the Council will receive an overview of the Spiny Dogfish 2019 Fishery Performance Report and the Spiny Dogfish Monitoring Committee's recommendations for the 2020 fishing year. Next, the Atlantic herring report will cover two issues. First, the Council will receive a presentation on the final discussion document pertaining to Atlantic herring spawning on Georges Bank. Second, the Council will receive the final debrief report on the Management Strategy Evaluation (MSE) process that was used to develop ABC control rule alternatives for Amendment 8 to the Atlantic Herring FMP. The Council then will hear from its Ecosystem-Based Fishery Management (EBFM) MSE Steering Committee, which will provide recommendations

on developing a non-technical document and structure for public information workshops, focusing on the approach used for the Council's example Fishery Ecosystem Plan for Georges Bank. Finally, the Council will receive an overview of NMFS's Modernizing Recreational Fisheries Management Act of 2018 Report to Congress and approve Council comment. Following these actions, the Council will adjourn for the day.

Wednesday, December 4, 2019

The Council will begin the day with a NEFSC presentation on the peer-reviewed results of the 2019 operational assessments for 14 Northeast multispecies (groundfish) stocks. Next, the Scientific and Statistical Committee (SSC) will provide the Council with overfishing limit (OFL) and ABC recommendations for those 14 groundfish stocks for fishing years 2020–22, as well as OFL and ABC recommendations for Atlantic sea scallops for fishing year 2020 with default specifications for 2021. The Groundfish Committee report will be next with three items. First, the Council will take final action on Framework Adjustment 59 to the Northeast Multispecies FMP. The framework includes: (1) 2020 total allowable catches for U.S./Canada stocks of Eastern Georges Bank (GB) cod, Eastern GB haddock, and GB yellowtail flounder; (2) 2020–22 specifications for 15 stocks, addressing commercial/recreational allocation if raised by data from the Marine Recreational Information Program (MRIP); and (3) removal of the allocation to the Closed Area I Haddock Special Access Program. This discussion will be followed by a progress report on Groundfish Monitoring Amendment 23, and then the Council will receive a summary of the input gathered during a series of public listening sessions that were conducted to gauge whether the Council should pursue developing a limited access program for the groundfish party/charter fishery.

Following the lunch break, the Council will continue its groundfish deliberations until all business is concluded. Then, the Council will receive a report on GARFO's October 2019 New England Recreational Fishing Workshops. After that, the Council will adjourn for the day.

Thursday, December 5, 2019

The third day of the meeting will begin with a discussion of Council priorities. The Council will take final action on 2020 priorities covering tasks and actions for all committees and Council responsibilities. Next, the Council will take up the Scallop Committee Report, which will cover two items. First, the Council will take final action on Framework Adjustment 32 to the Atlantic Sea Scallop FMP. This framework includes fishing year 2020 specifications, 2021 default specifications, and measures to mitigate impacts on Georges Bank yellowtail flounder. The Council also is working on Amendment 21 to the FMP, which is being developed to address: (1) Northern Gulf of Maine (NGOM) Management Area issues, (2) the Limited Access General Category (LAGC) possession limit, and (3) the one-way transfer of individual fishing quota (IFQ) from Limited Access vessels with LAGC IFQ to vessels that only hold LAGC IFQ permits. As part of this action, the Council will discuss whether or not to ask NMFS to publish a control date to restrict movement between LAGC permit categories. The Council may take action on this item.

Following the lunch break, the Council will receive a habitat report with updates on: (1) Ongoing offshore energy activities in the Northeast Region; and (2) habitat-related work. Next, the Council will receive a presentation from Cornell Cooperative Extension on its technology transfer program for small-mesh fishermen to utilize large-mesh belly panels to reduce bycatch of Georges Bank yellowtail flounder. This will be followed by the Council's small-mesh multispecies (whiting) report, which will focus on action being taken to rebuild southern red hake. Finally, the Council will close out the meeting with ''other business.''

Although non-emergency issues not contained on this agenda may come before the Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies (see **ADDRESSES**) at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 12, 2019.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2019–24788 Filed 11–14–19; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2019–0056]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is requesting to renew the Office of Management and Budget (OMB) approval for an existing information collection titled, ''Application Forms for Financial Empowerment Training Programs.''

DATES: Written comments are encouraged and must be received on or before January 14, 2020 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PRA_Comments@cfpb.gov.* Include Docket No. CFPB–2019–0056 in the subject line of the message.
- *Mail:* Comment Intake, Bureau of Consumer Financial Protection (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552.
- *Hand Delivery/Courier:* Comment Intake, Bureau of Consumer Financial Protection (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is

available at *www.regulations.gov.* Requests for additional information should be directed to Darrin King, PRA Officer, at (202) 435–9575, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Application Forms for Financial Empowerment Training Programs.

OMB Control Number: 3170–0068.

Type of Review: Revision of a currently approved collection.

Affected Public: Government social service entities, and not-for-profit institutions.

Estimated Number of Annual Respondents: 275.

Estimated Total Annual Burden Hours: 825.

Abstract: The Bureau's Office of Community Affairs (OCA) is responsible for developing strategies to improve the financial capability of low-income and economically vulnerable consumers, such as consumers who are unbanked or underbanked, those with thin or no credit file, and households with limited savings. To address the needs of these consumers, OCA has developed two initiatives that target intermediary organizations and provide tools, training, technical assistance, and other services to help them reach low-income and economically vulnerable consumers to provide them the financial empowerment tools and information that they need, when they need it, where they are. These initiatives: (1) Your Money, Your Goals, and (2) Tax Time Savings both require the Bureau to engage organizations to participate in our financial empowerment initiatives. The proposed information collection request consists of application forms that will be used by community-based organizations, local, State, or Federal government entities, and national non-profit organizations to indicate their desire and ability to participate in OCA's various initiatives. Empowerment will use the information provided in these applications to select the best qualified organizations for participation.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Dated: November 12, 2019.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2019–24799 Filed 11–14–19; 8:45 am]

BILLING CODE 4810–AM–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, November 20, 2019; 1:30–2:30 p.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, MD 20814.

STATUS: Commission Meeting—Open to the Public.

MATTER TO BE CONSIDERED: Briefing Matter: Staff will brief the Commission on the subject of ''Wearables''.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7479.

Dated: November 13, 2019.

Alberta E. Mills,

Secretary.

[FR Doc. 2019–24941 Filed 11–13–19; 4:15 pm]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2009–0088]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Third Party Conformity Assessment Body Registration Form

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC) announces that the CPSC has submitted to the Office of Management and Budget (OMB) a request for extension of approval of a collection of information under the requirements pertaining to the third party conformity assessment bodies registration form, approved previously under (OMB No. 3041–0143). In the **Federal Register** of September 6, 2019, the CPSC published a notice announcing the agency's intent to seek extension of approval of the collection of information. The Commission received no comments. Therefore, by publication of this notice, the CPSC announces that the agency has submitted to the OMB a request for extension of approval of that collection of information, without change.

DATES: Submit written comments on this request for extension of approval of information collection by December 16, 2019.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at *http://www.regulations.gov,* under Docket No. CPSC–2009–0088.

FOR FURTHER INFORMATION CONTACT: Bretford J. Griffin, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7037, or by email to: *bfriffin@cpsc.gov*.

SUPPLEMENTARY INFORMATION: CPSC has submitted the following currently approved collection of information to OMB for extension:

Title: Requirements Pertaining to Third Party Conformity Assessment Bodies.

OMB Number: 3041–0143.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Third party conformity assessment bodies seeking acceptance of accreditation or continuing accreditation.

General Description of Collection: The Consumer Product Safety Improvement Act of 2008 (CPSIA) requires certificates of conformity to be based in some cases on testing conducted by third party conformity assessment bodies. The CPSIA allows third party conformity assessment bodies to be accredited either by the Commission or by an independent accreditation organization designated by the Commission, and

requires that the Commission maintain on its website an up-to-date list of entities that have been accredited to assess conformity with specific children's product safety rules. Except for firewalled third party conformity assessment bodies, the Commission has chosen to accept the accreditation of third party conformity assessment bodies that meet accreditation requirements of an independent accreditation organization.

To evaluate a third party conformity assessment body's qualifications for acceptance by CPSC, information related to location, accreditation, and ownership must be collected from third party conformity assessment bodies. The CPSC uses an online collection form, CPSC Form 223, to gather information from third party conformity assessment bodies who are voluntarily seeking acceptance by CPSC. The information collected relates to location, accreditation, and ownership. CPSC staff uses this information to assess:

- A third party conformity assessment body's status as an independent third party conformity assessment body, a government-owned or government-controlled conformity assessment body, or a firewalled conformity assessment body;
- Qualifications for acceptance by CPSC to test for compliance to specified children's product safety rules; and
- Eligibility for acceptance on the CPSC website.

Part 1112 requires the collection of information in CPSC Form 223:

- Upon initial application by a third party conformity assessment body for acceptance by CPSC;
- Whenever there is a change in accreditation or ownership information; and
- At least every 2 years, as part of a regular audit process.

Estimated Burden:

The CPSC estimates the burden of the collection of information in CPSC Form 223 is as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Frequency of responses	Total annual responses	Hours per response	Total hours
Initial Registration	40	1	40	1	40
Re-Registration	291	1	291	1	291
Changes in Information	6	1	6	0.25	1.5
Total	.....	.....	.....	.....	332.5

These estimates are based on the following information:

- Based on applications received from FY 2013, to date, we estimate the number of third party conformity assessment bodies that would register initially each year for the next 3 years to be 40.
- Under 16 CFR part 1112, third party conformity assessment bodies are required to resubmit CPSC Form 223 every 2 years. Because all third party conformity assessment bodies have not submitted their first CPSC Form 223s at the same time, only about half would be expected to resubmit a CPSC Form 223 in any 1 year.
- As of August 2019, 581 third party conformity assessment bodies have registered with CPSC. Approximately half (291) of these firms would be required to re-register with CPSC each year.
- Under 16 CFR part 1112, third party conformity assessment bodies are required to ensure that the information submitted on CPSC Form 223 is current and must submit a new CPSC Form 223 whenever the information changes. Based on current experience with third party conformity assessment bodies, we estimate that two third party conformity assessment bodies will make revisions per year to update their information. A change in information is a change that does not require review of laboratory accreditation documents, such as scope or test methods. Examples of revised information include changes in the website URL, name of the laboratory, and name of point of contact.
- Therefore, the total burden is 332.5 hours, which we will round up to 333 hours. We estimate that hourly compensation for the time required for recordkeeping is $34.61 per hour (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' Table 9, total compensation for sales, office, and related workers in goods-producing industries, March 2019: *https://www.bls.gov/ect/data.htm*). The total cost burden to the respondents is approximately $11,525 ($34.61 × 333 hours = $11,525).

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2019–24784 Filed 11–14–19; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of Department of the Air Force

Notice of Intent To Grant an Exclusive Patent License

AGENCY: Department of the Air Force, DoD.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant an exclusive patent license agreement to The Board of Regents of the University of Texas System, an agency of the State of Texas, having a place of business at 210 West 7th Street, Austin, TX 78701.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to the Air Force Materiel Command Law Office, AFMCLO/JAZ, 2240 B Street, Room 260, Wright-Patterson AFB, OH 45433–7109; Facsimile: (937) 255–3733; or Email: *afmclo.jaz.tech@us.af.mil.* Include Docket No. AFD 1870 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Air Force Materiel Command Law Office, AFMCLO/JAZ, 2240 B Street, Rm 260, Wright-Patterson AFB, OH 45433–7109; Facsimile: (937) 255–3733; Email: *afmclo.jaz.tech@us.af.mil.*

SUPPLEMENTARY INFORMATION: The Department of the Air Force intends to grant the exclusive patent license agreement to consolidate rights with co-owner The Board of Regents of the University of Texas System for the invention described in: U.S. Patent Application Serial No. 62/748,888, filed October 22, 2018, and entitled ''Multilayered Sheet-Polarizers with Enhanced Polarization Ratio and High Power Tolerance.''

The consolidation of rights is in the best interest of both owners in order to promote commercialization of the technology. The Department of the Air

Force may grant the prospective license unless a timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Adriane Paris,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2019–24704 Filed 11–14–19; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2019–HQ–0014]

Submission for OMB Review; Comment Request

AGENCY: Navy Personnel Command (PERS–13) Navy Casualty, Navy, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 16, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Collection of Personal Information for Casualty Benefits; OPNAV Form 1770/1,''Consent to Release Personal Information''; OPNAV Form 1770/2, ''Next of Kin Travel Request''; OPNAV Form 1770/3, ''Next of Kin Identification''; OMB Control Number 0703–XXXX.

OPNAV 1770/1

Annual Burden Hours: 300.
Number of Respondents: 600.
Responses per Respondent: 1.
Annual Responses: 600.
Average Burden per Response: 30 minutes.
Frequency: As required.

OPNAV 1770/2

Annual Burden Hours: 400.
Number of Respondents: 800.
Responses per Respondent: 1.
Annual Responses: 800.
Average Burden per Response: 30 minutes.
Frequency: As required.

OPNAV 1770/3

Annual Burden Hours: 600.
Number of Respondents: 600.
Responses per Respondent: 1.
Annual Responses: 600.
Average Burden per Response: 1 hour.
Frequency: As required.
Total Number of Respondents: 800 (600 will complete all three forms, 200 more will complete form 1770/2).
Total Number of Annual Responses: 800.
Total Respondent Burden Hours: 1,300.
Needs and Uses: The information is collected from the next of kin (NOK) and other beneficiaries following the death of a Navy Sailor. Basic contact information is passed to members of Congress and the White House (when consent is granted) for use in condolence activity. This and additional information collected is necessary to review, certify, and process payment of benefits awarded to designated NOK and other beneficiaries following the death. The form gathers data necessary to facilitate direct payment of benefits through the Defense Finance and Accounting Agency (DFAS), arrange travel to memorial and funeral services through the Defense Travel System (DTS), and to process travel claims submitted post-travel through DTS to DFAS. Data on the form is used solely for these functions.
Affected Public: Individuals or households.
Respondent's Obligation: Voluntary.
OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 8, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–24779 Filed 11–14–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2019–ICCD–0102]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; State and Local Educational Agency Record and Reporting Requirements Under Part B of the Individuals With Disabilities Education Act

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before December 16, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0102. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by

postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W–208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Rebecca Walawender, 202–245–7399.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: State and Local Educational Agency Record and Reporting Requirements under Part B of the Individuals with Disabilities Education Act.

OMB Control Number: 1820–0600.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 73,623.

Total Estimated Number of Annual Burden Hours: 362,649.

Abstract: OMB Information Collection 1820–0600 reflects the provisions in the Act and the Part B regulations requiring States and/or local educational agencies (LEAs) to collect and maintain information or data and, in some cases, report information or data to other public agencies or to the public. However, some of the information or data are not reported to the Secretary. Data are collected in the areas of private schools, parentally placed private school students, State high cost fund, notification of free and low cost legal services, early intervening services, notification of hearing offices and mediators, State complaint procedures, significant disproportionality, and the LEA application under Part B.

Dated: November 12, 2019.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2019–24813 Filed 11–14–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2019–ICCD–0103]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Annual State Application Under Part B of the Individuals With Disabilities Education Act as Amended in 2004

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before December 16, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0103. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave SW, LBJ, Room 6W–208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Rebecca Walawender, 202–245–7399.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Annual State Application Under Part B of the Individuals with Disabilities Education Act as Amended in 2004.

OMB Control Number: 1820–0030.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 60.

Total Estimated Number of Annual Burden Hours: 2,340.

Abstract: The Individuals with Disabilities Education Act, signed on December 3, 2004, became Public Law 108–446. In accordance with 20 U.S.C. 1412(a) a State is eligible for assistance under Part B for a fiscal year if the State submits a plan that provides assurances to the Secretary that the State has in

effect policies and procedures to ensure that the State meets each of the conditions found in 20 U.S.C. 1412. Information collection 1820–0030 allows States to proved assurances that it either has or does not have in effect policies and procedures to meet the eligibility requirements of Part B of th Act as found in Public Law 108–446.

Information Collection 1820–0030 is being revised to include the reporting requirement in 34 CFR 300.647(b)(7). This requirement is pursuant to the significant disproportionality rules promulgated on December 19, 2016.

Dated: November 12, 2019.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2019–24823 Filed 11–14–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Intent to Revise Power Marketing Policy Kerr-Philpott System of Projects

AGENCY: Southeastern Power Administration (Southeastern), DOE.

ACTION: Notice of Intention to begin a public process.

SUMMARY: Pursuant to its Procedure for Public Participation in the Formulation of Marketing Policy, published in the **Federal Register** of July 6, 1978, Southeastern Power Administration (Southeastern) intends to revise its marketing policy by including provisions regarding renewable energy certificates from its Kerr-Philpott System of Projects. The current power marketing policy was published on July 29, 1985, for the Southeastern Kerr-Philpott System and is reflected in contracts for the sale of system power, which are maintained in Southeastern's headquarters office. Southeastern solicits written comments and proposals in formulating the proposed marketing policy revision.

DATES: Comments and proposals must be submitted on or before January 14, 2020.

ADDRESSES: Written comments or proposals should be submitted to Kenneth E. Legg, Administrator, Southeastern Power Administration, 1166 Athens Tech Road, Elberton, GA 30635–6711, (706) 213–3800, *Comments@sepa.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Leon Jourolmon IV, General Counsel, (706) 213–3800, *Comments@sepa.doe.gov.*

SUPPLEMENTARY INFORMATION: A ''Final Power Marketing Policy Kerr-Philpott System of Projects'' was developed and published in the **Federal Register** on July 29, 1985, 50 FR 30752, by Southeastern. The policy establishes the marketing area for system power and addresses the utilization of area utility systems for essential purposes. The policy also addresses wholesale rates, resale rates, and conservation measures, but does not address renewable energy certificates.

Under Section 5 of the Flood Control Act of 1944 (16 U.S.C. 825s), Southeastern is responsible for the transmission and disposition of electric power and energy from reservoir projects operated by the Department of the Army. Furthermore, Southeastern must transmit and dispose of such power and energy in such manner as to encourage the most widespread use at the lowest possible rates to consumers consistent with sound business principles. Rate schedules are drawn having regard to the recovery of the cost of producing and transmitting such electric energy.

The Kerr-Philpott System consists of two projects, the John H. Kerr Project and the Philpott Project. The power from the projects is currently marketed to Preference Customers located in the service areas of Dominion Energy, Duke Energy Progress, American Municipal Power, and American Electric Power.

Both the John H. Kerr Project and the Philpott Project are located within the regional footprint served by the regional transmission organization PJM Interconnection, L.L.C. (PJM) footprint, as are the Virginia-based Preference Customers with power allocations. Southeastern owns no transmission assets in the area of the Kerr-Philpott System and relies on PJM transmission resources to dispose of power and energy from the projects. As such, Southeastern joined PJM in 2005.

As the projects are located within the PJM region and potentially satisfy Renewable Portfolio Standards in a number of states, Southeastern has subscribed to the PJM Generation Attribute Tracking System (GATS). The GATS provides an unbundled, certificates-based tracking system that reports certain operating attributes of electricity generators selling energy through the PJM Market Settlement System. The attributes are unbundled from the megawatt-hour of energy produced and recorded onto a certificate. These certificates may be used by electricity suppliers and other energy market participants to comply with relevant state policies and regulatory programs and to support voluntary ''green'' electricity markets. Southeastern is considering distributing the GATS-created certificates to current Preference Customers with allocations of power from the Kerr-Philpott System.

Upon formulating a proposed revision to the Kerr-Philpott System marketing policy to address renewable energy certificates, Southeastern will publish the proposal in the **Federal Register** and begin a sixty-day comment period pursuant to its Procedures for Public Participation in the Formulation of Marketing Policy.

Dated: November 7, 2019.

Kenneth E. Legg,

Administrator.

[FR Doc. 2019–24819 Filed 11–14–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–512–000]

Texas Eastern Transmission, L.P.; Notice of Intent To Prepare an Environmental Assessment for the Proposed Cameron Extension Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Cameron Extension Project involving construction of a new 30,000 horsepower compressor station by Texas Eastern Transmission, L.P. (Texas Eastern), in Calcasieu Parish, Louisiana. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies about issues regarding the project. The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires the Commission to discover concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in

the EA. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on December 9, 2019.

You can make a difference by submitting your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Commission staff will consider all filed comments during the preparation of the EA.

If you sent comments on this project to the Commission before the opening of this docket on September 26, 2019, you will need to file those comments in Docket No. CP19–512–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law.

Texas Eastern provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC website (*www.ferc.gov*) at *https://www.ferc.gov/resources/guides/gas/gas.pdf.*

Public Participation

The Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. To sign up go to *www.ferc.gov/docs-filing/esubscription.asp.*

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature, which is also on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.*'' You will be asked to select the type of filing you are making; a comment on a particular project is considered a ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (CP19–512–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

Summary of the Proposed Project

Texas Eastern proposes to construct and operate a new compressor station (East Calcasieu Compressor Station) in Calcasieu Parish, Louisiana. The new compressor station is comprised of one 30,000 ISO-rated horsepower, natural gas-driven turbine compressor unit and related appurtenances. The project would consist of the following new facilities:

- Installation of a new delivery meter and regulatory (M&R) station and related facilities, including 0.2 mile of 30-inch-diameter piping to interconnect with TransCameron, LLC's pipeline system in Cameron Parish, Louisiana;
- installation of a receipt M&R station and related facilities at a new interconnect with Momentum Midstream, LLC in Beareugard Parish, Louisiana;
- installation of a new bi-directional M&R station and related facilities at a new interconnect with Trunkline Gas Company, LLC in Jefferson Davis Parish, Louisiana;
- installation of equipment, including a filter separator and regulator at the Gillis Compressor Station in Beauregard Parish, Louisiana;
- modifications to existing internal pipeline inspection launcher and receiver facilities, as well as two new bypass facilities at existing sites along Texas Eastern's Line 41 in Cameron (Grand Chenier Compressor Station), Beuregard (Gillis Compressor Station), and Jefferson Davis (Iowa Plant) Parishes, Louisiana; and
- other related auxiliary facilities and appurtenances.

The project would reverse natural gas flow on a portion of Texas Eastern's Line 41 mainline to provide natural gas from various sources to serve the Venture Global Calcasieu Pass Terminal, a liquefied natural gas export terminal project currently under development in Cameron Parish, Louisiana. Texas Eastern proposes to provide 750 million cubic feet per day of firm transportation service. Texas Eastern proposes to complete and place this project into service by November 1, 2021.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

Construction of the project would disturb about 156.8 acres (of which 81.7 acres would be within the existing fence line of the Gillis Compressor Station, Iowa Plant, and Grand Chenier Compressor Station facility). Texas Eastern would maintain 10.2 acres for permanent operation of the project's facilities following construction. The remaining acreage would be restored and revert to former uses.

The EA Process

The EA will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- water resources and wetlands;
- vegetation and wildlife;

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE, Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

- threatened and endangered species;
- cultural resources;
- land use;
- air quality and noise;
- public safety; and
- cumulative impacts.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present Commission staffs' independent analysis of the issues. The EA will be available in electronic format in the public record through eLibrary [2] and the Commission's website (*https://www.ferc.gov/industries/gas/enviro/eis.asp*). If eSubscribed, you will receive instant email notification when the EA is issued. The EA may be issued for an allotted public comment period. Commission staff will consider all comments on the EA before making recommendations to the Commission. To ensure Commission staff have the opportunity to address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office, and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] The EA for this project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes: Federal, state, and local government representatives and agencies; elected officials; Native American Tribes; libraries; newspapers; and other interested parties. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If the Commission issues the EA for an allotted public comment period, a *Notice of Availability* of the EA will be sent to the environmental mailing list and will provide instructions to access the electronic document on the FERC's website (*www.ferc.gov*). If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please return the attached ''Mailing List Update Form'' (appendix 2).

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.,* CP19–512). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: November 8, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24815 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

[2] For instructions on connecting to eLibrary, refer to the last page of this notice.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–479–000]

Northern Natural Gas Company; Notice of Revised Schedule for Environmental Review of the Bushton to Clifton A-Line Abandonment Project

This notice identifies the Federal Energy Regulatory Commission (FERC) staff's revised schedule for the completion of the environmental assessment (EA) for Northern Natural Gas Company's Bushton to Clifton A-Line Abandonment Project. The first notice of schedule, issued on July 30, 2019, identified November 8, 2019 as the EA issuance date.

Because affected landowners were inadvertently excluded from the environmental mailing list for the *Notice of Intent to Prepare an Environmental Assessment for the Proposed Bushton to Clifton A-line Abandonment Project* issued by the Commission on July 15, 2019, we have issued a supplemental notice on November 6, 2019 to provide all affected landowners an opportunity to comment in this proceeding. As a result, staff has revised the schedule for issuance of the EA to extend the comment period and give the public an expanded opportunity to participate in the project's design and implementation.

Schedule for Environmental Review

Issuance of Notice of Availability of the EA—December 17, 2019
90-day Federal Authorization Decision Deadline—March 16, 2019

If a schedule change becomes necessary, an additional notice will be provided so that the relevant agencies are kept informed of the project's progress.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the

documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Additional information about the project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the eLibrary link, select ''General Search'' from the eLibrary menu, enter the selected date range and Docket Number excluding the last three digits (*i.e.,* CP19–479), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: November 7, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24767 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–474–000]

Notice of Revised Schedule for Environmental Review of the Florida Gas Transmission Company, LLC Putnam Expansion Project

This notice identifies the Federal Energy Regulatory Commission staff's revised schedule for the completion of the environmental assessment (EA) for Florida Gas Transmission Company, LLC's Putnam Expansion Project. The first notice of schedule, issued on August 14, 2019, identified November 8, 2019 as the EA issuance date. However, Florida Gas Transmission Company filed additional information on November 5, 2019 in response to Commission staff's October 30, 2019 data request regarding an affected landowner comment that was filed in this proceeding. Because the requested information was necessary to complete the environmental review, staff has revised the schedule for issuance of the EA.

Schedule for Environmental Review

Issuance of Notice of Availability of the EA—December 6, 2019

90-day Federal Authorization Decision Deadline—March 5, 2020

If a schedule change becomes necessary, an additional notice will be provided so that the relevant agencies are kept informed of the project's progress.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the eLibrary link, select General Search from the eLibrary menu, enter the selected date range and Docket Number excluding the last three digits (*i.e.,* CP19–474), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: November 7, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24766 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR20–6–000.
Applicants: Pelico Pipeline, LLC.
Description: Tariff filing per 284.123(b)(2)+(g): Pelico Pipeline, LLC Petition for Rate Approval & Revised SOC to be effective 11/1/2019.
Filed Date: 11/6/19.
Accession Number: 201911065050.
Comments Due: 5 p.m. ET 11/27/19.
284.123(g) Protests Due: 5 p.m. ET 1/6/20.

Docket Number: PR20–7–000.
Applicants: Intrastate Gas LP.
Description: Tariff filing per 284.123(b)(2)+(g): Regency Intrastate Gas LP Petition for Rate Approval & Revised SOC to be effective 11/1/2019.
Filed Date: 11/6/19.
Accession Number: 201911065050.
Comments Due: 5 p.m. ET 11/27/19.
284.123(g) Protests Due: 5 p.m. ET 1/6/20.

Docket Numbers: RP20–208–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Nov 2019 Negotiated Rates Cleanup Filing to be effective 12/6/2019.
Filed Date: 11/6/19.
Accession Number: 20191106–5009.
Comments Due: 5 p.m. ET 11/18/19.

Docket Numbers: RP20–209–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: § 4(d) Rate Filing: Balancing Service Charges Penalty Tolerance Filing to be effective 1/1/2020.
Filed Date: 11/6/19.
Accession Number: 20191106–5012.
Comments Due: 5 p.m. ET 11/18/19.

Docket Numbers: RP20–210–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate 2019–11–6 ConocoPhillips to be effective 11/6/2019.
Filed Date: 11/6/19.
Accession Number: 20191106–5060.
Comments Due: 5 p.m. ET 11/18/19.

Docket Numbers: RP20–211–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Momentum Rate Filing—Zone 5–5 to be effective 12/7/2019.
Filed Date: 11/6/19.
Accession Number: 20191106–5160.
Comments Due: 5 p.m. ET 11/18/19.

Docket Numbers: RP20–212–000.
Applicants: Enable Mississippi River Transmission, LLC.
Description: Compliance filing Offer of Settlement of MRT under RP20–131–000 to be effective 12/1/2019.
Filed Date: 11/6/19.
Accession Number: 20191106–5165.
Comments Due: 5 p.m. ET 11/18/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 7, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24765 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG20–27–000.

Applicants: Bitter Ridge Wind Farm, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Bitter Ridge Wind Farm, LLC.

Filed Date: 11/8/19.

Accession Number: 20191108–5109.

Comments Due: 5 p.m. ET 11/29/19.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC20–5–000.

Applicants: 83WI 8me, LLC, Blue Canyon Windpower LLC, Burgess Biopower LLC, Dempsey Ridge Wind Farm, LLC, EcoGrove Wind, LLC, Flat Water Wind Farm, LLC, Lily Solar, LLC, Lily Solar Lessee, LLC, Persimmon Creek Wind Farm 1, LLC, Red Hills Wind Project, L.L.C., Roth Rock Wind Farm, LLC, Tatanka Wind Power, LLC, TPW Petersburg, LLC, X-elio Energy SC York, LLC, Brookfield Renewable Power Ltd., Longview Power, LLC, Nevada Solar One, LLC.

Description: Supplement to October 4, 2019 Application for Authorization Under Section 203 of the Federal Power Act, et al. of 83WI 8me, LLC, et al.

Filed Date: 11/8/19.

Accession Number: 20191108–5104.

Comments Due: 5 p.m. ET 11/18/19.

Docket Numbers: EC20–15–000.

Applicants: Bicent (California) Malburg LLC, BIV Generation Company, L.L.C., Cayuga Operating Company, LLC, Colorado Power Partners, Somerset Operating Company, LLC, Tanner Street Generation, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Bicent (California) Malburg LLC, et al.

Filed Date: 11/7/19.

Accession Number: 20191107–5199.

Comments Due: 5 p.m. ET 11/29/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER19–1077–002.

Applicants: Wildcat Wind Farm I, LLC.

Description: Compliance filing: Compliance Filing Under Docket ER19–1077–000 to be effective 4/20/2019.

Filed Date: 11/8/19.

Accession Number: 20191108–5007.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER19–1683–000; *TS19–3–000.*

Applicants: Wildhorse Wind Energy, LLC, Southern Power Company.

Description: Amendment to April 26, 2019 Petition for Waiver of the requirement of Order Nos. 888, et al. of Wildhorse Wind Energy, LLC.

Filed Date: 11/8/19.

Accession Number: 20191108–5092.

Comments Due: 5 p.m. ET 11/18/19.

Docket Numbers: ER20–99–001.

Applicants: Evergy Kansas Central, Inc.

Description: Compliance filing: Amendment to a Notice of Succession & Refile Tariff (Baseline Filing), OATT to be effective 12/16/2019.

Filed Date: 11/8/19.

Accession Number: 20191108–5074.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–335–000.

Applicants: McKenzie Electric Cooperative, Inc.

Description: Baseline eTariff Filing: Initial Filing of Generating Facility Interconnection Agreement to be effective 11/8/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5164.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–336–000.

Applicants: Jersey Central Power & Light Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: JCP&L submits Interconnection Agreement SA No. 4920 to be effective 1/6/2020.

Filed Date: 11/7/19.

Accession Number: 20191107–5165.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–337–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4386; Queue No. AB1–049 to be effective 11/12/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5166.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–338–000; *TS20–1–000.*

Applicants: McKenzie Electric Cooperative, Inc.

Description: Request for Waiver of Open-Access Requirements of Order Nos. 888, et al. of McKenzie Electric Cooperative, Inc.

Filed Date: 11/7/19.

Accession Number: 20191107–5201.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–339–000.

Applicants: Twiggs County Solar, LLC.

Description: Baseline eTariff Filing: Application for Market Based Rate to be effective 11/14/2019.

Filed Date: 11/8/19.

Accession Number: 20191108–5033.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–340–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: DEC–DEP SA No. 514 ASOA (Asheville CC) to be effective 11/15/2019.

Filed Date: 11/8/19.

Accession Number: 20191108–5059.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–341–000.

Applicants: Duke Energy Progress, LLC.

Description: § 205(d) Rate Filing: DEP–DEC Asheville CC ASOA Concurrence Filing (SA No. 362) to be effective 11/15/2019.

Filed Date: 11/8/19.

Accession Number: 20191108–5061.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–342–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation WMPA/SA No. 4387; Queue No. AB1–050 to be effective 11/12/2019.

Filed Date: 11/8/19.

Accession Number: 20191108–5073.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–343–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4388; Queue No. AB1–051 to be effective 11/12/2019.

Filed Date: 11/8/19.

Accession Number: 20191108–5103.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–344–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4389; Queue No. AB1–052 to be effective 11/12/2019.

Filed Date: 11/8/19.
Accession Number: 20191108–5121.
Comments Due: 5 p.m. ET 11/29/19.
Docket Numbers: ER20–345–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: Notice of Termination of the PARS Facilities Agreement of New York Independent System Operator, Inc., on behalf of Consolidated Edison Company of New York, Inc.
Filed Date: 11/8/19.
Accession Number: 20191108–5128.
Comments Due: 5 p.m. ET 11/29/19.
Docket Numbers: ER20–346–000.
Applicants: Startrans IO, LLC.
Description: § 205(d) Rate Filing: TRBAA 2020 Update to be effective 1/1/2020.
Filed Date: 11/8/19.
Accession Number: 20191108–5153.
Comments Due: 5 p.m. ET 11/29/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 8, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24812 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14873–001]

Nushagak Electric & Telephone Cooperative, Inc.; Notice of Intent To File License Application, Filing of Pre-Application Document, Commencement of Pre-Filing Process, and Scoping; Request for Comments on the Pad and Scoping Document, and Identification of Issues and Associated Study Requests

a. *Type of Filing:* Notice of Intent to File License Application for an Original License and Commencing Pre-filing Process.

b. *Project No.:* 14873–001.

c. *Dated Filed:* October 7, 2019.

d. *Submitted By:* Nushagak Electric & Telephone Cooperative, Inc.

e. *Name of Project:* Nuyakuk River Hydroelectric Project.

f. *Location:* On the Nuyakuk River, in the Dillingham Census Area, Alaska. The project occupies 357 acres of United States lands under the jurisdiction of the Bureau of Land Management.

g. *Filed Pursuant to:* 18 CFR part 5 of the Commission's Regulations.

h. Potential *Applicant Contact:* Mr. Bobby Armstrong, Nushagak Electric & Telephone Cooperative, Inc., P.O. Box 350, Dillingham, Alaska 99576; phone: (907) 842–5251 or email at *barmstrong@nushagak.coop.*

i. *FERC Contact:* Julia Kolberg at (202) 502–8261 or email at *julia.kolberg@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item o below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. With this notice, we are initiating informal consultation with: (a) The U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402 and (b) the State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. Nushagak Cooperative, Inc. filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

m. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCONlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in paragraph h.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. With this notice, we are soliciting comments on the PAD and Commission's staff Scoping Document 1 (SD1), as well as study requests. All comments on the PAD and SD1, and study requests should be sent to the address above in paragraph h. In addition, all comments on the PAD and SD1, study requests, requests for cooperating agency status, and all communications to and from Commission staff related to the merits of the potential application must be filed with the Commission.

The Commission strongly encourages electronic filing. Please file all documents using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov.* In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–14873–001.

All filings with the Commission must bear the appropriate heading: ''Comments on Pre-Application Document,'' ''Study Requests,'' ''Comments on Scoping Document 1,'' ''Request for Cooperating Agency Status,'' or ''Communications to and from Commission Staff.'' Any individual or entity interested in submitting study requests, commenting on the PAD or SD1, and any agency requesting cooperating status must do so by February 4, 2020.

p. Although our current intent is to prepare an environmental assessment (EA), there is the possibility that an Environmental Impact Statement (EIS) will be required. Nevertheless, this meeting will satisfy the NEPA scoping requirements, irrespective of whether an EA or EIS is issued by the Commission.

Scoping Meetings

Commission staff will hold two scoping meetings in the vicinity of the

project at the times and places noted below. The daytime meeting will focus on resource agency, Indian tribes, and non-governmental organization concerns, while the evening meeting is primarily for receiving input from the public. We invite all interested individuals, organizations, and agencies to attend one or both of the meetings, and to assist staff in identifying particular study needs, as well as the scope of environmental issues to be addressed in the environmental document. Teleconferencing capability will be provided for those who cannot attend the meeting in person. The times and locations of these meetings are as follows:

Daytime Scoping Meeting

Date: Wednesday, December 11, 2019.
Time: 10:00 a.m.
Location: Homewood Suites, 101 W. 48th Ave., Anchorage, AK 99503.
Phone: (907) 762–7000.

Evening Scoping Meeting

Date: Wednesday, December 11, 2019.
Time: 7:00 p.m.
Location: Homewood Suites, 101 W. 48th Ave., Anchorage, AK 99503.
Phone: (907) 762–7000.

Please notify Julia Kolberg at (202) 502–8261 or *Julia.kolberg@ferc.gov* on or before December 4, 2019, if you plan to attend scoping meetings via teleconference.

Scoping Document 1 (SD1), which outlines the subject areas to be addressed in the environmental document, was mailed to the individuals and entities on the Commission's mailing list. Copies of SD1 will be available at the scoping meetings, or may be viewed on the web at *http://www.ferc.gov,* using the ''eLibrary'' link. Follow the directions for accessing information in paragraph n. Based on all oral and written comments, a Scoping Document 2 (SD2) may be issued. SD2 may include a revised process plan and schedule, as well as a list of issues, identified through the scoping process.

Meeting Objectives

At the scoping meetings, staff will: (1) Initiate scoping of the issues; (2) review and discuss existing conditions and resource management objectives; (3) review and discuss existing information and identify preliminary information and study needs; (4) review and discuss the process plan and schedule for pre-filing activity that incorporates the time frames provided for in Part 5 of the Commission's regulations and, to the extent possible, maximizes coordination of federal, state, and tribal permitting and certification processes; and (5) discuss the appropriateness of any federal or state agency or Indian tribe acting as a cooperating agency for development of an environmental document.

Meeting participants should come prepared to discuss their issues and/or concerns. Please review the PAD in preparation for the scoping meetings. Directions on how to obtain a copy of the PAD and SD1 are included in item n. of this document.

Meeting Procedures

The meetings will be recorded by a stenographer and will be placed in the public records of the project.

Under the Commission's Integrated Licensing Process, the Commission conducts scoping within 90 days of the filing of the licensee's NOI. An environmental site review is typically held in conjunction with that scoping meeting. However, in this case, access to project facilities is likely to be limited by winter weather conditions when scoping for this project will occur. For this reason, the license applicant will play a video filmed during a flyover of the proposed project site. An environmental site review may be conducted at a later date. Therefore, we are waiving § 5.8(b)(viii) of the Commission's regulations requiring an environmental site review within 30 days of issuance of a notice of commencement of proceeding to facilitate the early environmental site review.

Dated: November 8, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24814 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC19–39–000]

Commission Information Collection Activities (FERC–511); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection FERC–511 (Transfer of Hydropower License) and submitting the information collection to the Office of Management and Budget (OMB) for review. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. On August 29, 2019, the Commission published a Notice in the **Federal Register** (84 FR 45489) in Docket No. IC19–39–000 requesting public comments. The Commission received no public comments.

DATES: Comments on the collection of information are due December 16, 2019.

ADDRESSES: Comments filed with OMB, identified by OMB Control No. 1902–0069, should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Officer.

A copy of the comments should also be sent to the Commission, in Docket No. IC19–39–000, by either of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–511, Transfer of Hydropower License.[1]

OMB Control No.: 1902–0069.

Type of Request: Three-year extension of the FERC–511 information collection requirements with no changes to the current reporting and recordkeeping requirements.

Abstract: The Commission uses the information collected under the

[1] The title is being updated to Transfer of Hydropower License (rather than Transfer of Electric License).

requirements of FERC–511 to implement the statutory provisions of Sections 4(e) and 8 of the Federal Power Act (FPA).[2] Section 4(e) authorizes the Commission to issue licenses for the construction, operation and maintenance of reservoirs, powerhouses, and transmission lines or other facilities necessary for the development and improvement of navigation and for the development, transmission, and utilization of power.[3] Section 8 of the FPA provides that the voluntary transfer of any license is made only with the written approval of the Commission. Any successor to the licensee may assign the rights of the original licensee but is subject to all of the conditions of the license. The information filed with the Commission is a mandatory requirement contained in the format of a written application for transfer of license, executed jointly by the parties of the proposed transfer. The sale or merger of a licensed hydroelectric project may occasion the transfer of a license. The Commission's staff uses the information collection to determine the qualifications of the proposed transferee to hold the license and to prepare the transfer of the license order. Approval by the Commission of transfer of a license is contingent upon the transfer of title to the properties under license, delivery of all license instruments, and evidence that such transfer is in the public interest. The Commission implements these filing requirements in the Code of Federal Regulations (CFR) under 18 CFR part 9.

Type of Respondent: Hydropower Project Licensees.

Estimate of Annual Burden:[4] The Commission estimates the annual burden and cost[5] for the information collection as follows.

FERC–511: TRANSFER OF HYDROPOWER LICENSE

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hrs. & cost per response	Total annual burden hours & total annual cost	Cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Hydropower Project Licensees	46	1	46	40 hrs.; $3,200	1,840 hrs.; $147,000	$3,200

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: November 7, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24768 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG20–26–000.

Applicants: Crowned Ridge Interconnection, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Crowned Ridge Interconnection, LLC.

Filed Date: 11/6/19.

Accession Number: 20191106–5133.

Comments Due: 5 p.m. ET 11/27/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–2318–007; ER16–2515–002; ER16–2278–002; ER13–2317–007; ER13–2319–007; ER17–2577–002.

Applicants: All Dams Generation, LLC, Black River Hydroelectric, LLC, Cube Yadkin Generation LLC, Lake Lynn Generation, LLC, PE Hydro Generation, LLC, York Haven Power Company, LLC.

Description: Notice of Non-Material Change in Status of All Dams Generation, LLC, et al.

Filed Date: 11/6/19.

Accession Number: 20191106–5182.

Comments Due: 5 p.m. ET 11/27/19.

Docket Numbers: ER17–556–002.

Applicants: Grady Wind Energy Center, LLC.

Description: Notice of Non-Material Change in Status of Grady Wind Energy Center, LLC.

Filed Date: 11/7/19.

Accession Number: 20191107–5110.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER19–2392–000.

Applicants: Chief Conemaugh Power II, LLC.

Description: Report Filing: Notice of Effective Date to be effective N/A.

Filed Date: 10/30/19.

Accession Number: 20191030–5101.

Comments Due: 5 p.m. ET 11/20/19.

Docket Numbers: ER19–2393–000.

Applicants: Chief Keystone Power II, LLC.

Description: Report Filing: Notice of Effective Date to be effective N/A.

Filed Date: 10/30/19.

Accession Number: 20191030–5104.

Comments Due: 5 p.m. ET 11/20/19.

Docket Numbers: ER20–325–000.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Notice of Cancellation of Service Agreement Nos. 1012 and 944; Queues K01 & G44 to be effective N/A.

Filed Date: 11/6/19.

Accession Number: 20191106–5130.

Comments Due: 5 p.m. ET 11/27/19.

Docket Numbers: ER20–326–000.

[2] 16 U.S.C. 797(e) and 801.

[3] Refers to facilities across, along, from, or in any of the streams or other bodies of water over which Congress has jurisdiction under its authority to regulate commerce with foreign nations and among the several States, or upon any part of public lands and reservations of the United States, or for the purpose of utilizing the surplus water or water power from any Government dam.

[4] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. See 5 CFR 1320 for additional information on the definition of information collection burden.

[5] The FERC 2019 average salary plus benefits for one FERC full-time equivalent (FTE) is $167,091/year (or $80.00/hour). Commission staff estimates that the industry's skill set (wages and benefits) for completing and filing FERC–511 is comparable to the Commission's skill set.

Applicants: The Dayton Power and Light Company, Ohio Power Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: DPL and Ohio Power submit Interconnection Agreement SA No. 1461 to be effective 1/6/2020.

Filed Date: 11/6/19.

Accession Number: 20191106–5159.

Comments Due: 5 p.m. ET 11/27/19.

Docket Numbers: ER20–327–000.

Applicants: Midcontinent Independent System Operator, Inc., American Electric Power Service Corporation.

Description: § 205(d) Rate Filing: 2019–11–07_SA 1524 I&M–NIPSCO Interconnection Agreement 3rd Rev to be effective 10/17/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5030.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–328–000.

Applicants: Sierra Pacific Power Company.

Description: § 205(d) Rate Filing: Service Agreement Nos. 16–00063 and 18–00023 Amended to be effective 11/1/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5049.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–329–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4383; Queue No. AB1–046 to be effective 11/12/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5052.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–330–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4384; Queue No. AB1–047 to be effective 11/12/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5097.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–331–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original ICSA SA No. 5500; Queue No. AC1–216 to be effective 10/8/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5106.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–332–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2019–11–07_SA 2872 Montana Dakota-Montana Dakota 2nd Rev. GIA (J405) to be effective 10/23/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5111.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–333–000.

Applicants: San Diego Gas & Electric Company.

Description: § 205(d) Rate Filing: First Amended and Restated Engineering & Procurement Agreement to be effective 11/8/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5112.

Comments Due: 5 p.m. ET 11/29/19.

Docket Numbers: ER20–334–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4385; Queue No. AB1–048 to be effective 11/12/2019.

Filed Date: 11/7/19.

Accession Number: 20191107–5142.

Comments Due: 5 p.m. ET 11/29/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 7, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24770 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10684–095]

City of Lansing, MI; Notice of Application for Surrender of License, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Application for surrender of minor license.

b. *Project No:* 10684–095.

c. *Date Filed:* September 30, 2019.

d. *Applicant:* City of Lansing, Michigan.

e. *Name of Project:* Moores Park Hydroelectric Project.

f. *Location:* The 600-kilowatt project is located on the Grand River, in the City of Lansing, Ingham County, Michigan. The project does not occupy any federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Lori Myott, Manager, Environmental Services Department, Lansing Board of Water and Light, 1201 South Washington Avenue, Lansing, MI 48910–1650, 517–702–6639, or *Lori.Myott@lbwl.com.*

i. *FERC Contact:* Diana Shannon, (202) 502–6136, *diana.shannon@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* December 9, 2019.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–10684–095. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The applicant proposes to surrender its license for the project. The project has not operated since 2013 due to mechanical equipment problems. No ground disturbance is proposed and

project features will remain in place. The applicant would retain ownership of the dam and maintain the current reservoir elevation of 833.4 ± 0.2 NGVD29. In order to decommission the project facilities, the applicant proposes to close the intake for the units with steel bulkheads and to disconnect the project generators from the grid. The applicant proposes to keep the generating equipment in place. The powerhouse would remain secured with the existing fencing and security system. The current license expires on December 31, 2023.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title COMMENTS, PROTEST, or MOTION TO INTERVENE as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: November 7, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24769 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP19–491–000; CP19–494–000]

National Fuel Gas Supply Corporation and Transcontinental Gas Pipe Line Company, LLC; Notice of Schedule For Environmental Review of The FM100 Project and Leidy South Project

On July 18, 2019 and July 31, 2019, National Fuel Gas Supply Corporation (National Fuel) and Transcontinental Gas Pipe Line Company, LLC (Transco) filed their respective applications in Docket Nos. CP19–491–000 and CP19–494–000 each requesting a Certificate of Public Convenience and Necessity pursuant to Sections 7(b) and 7(c) of the Natural Gas Act to construct, operate, and abandon certain natural gas pipeline facilities. The proposed projects are the FM100 Project, proposed by National Fuel, and the Leidy South Project, proposed by Transco (Projects). The FM100 Project would allow National Fuel to modernize a portion of its existing system and provide an additional 330,000 dekatherms per day (Dth/d) of incremental natural gas transportation capacity, all of which is fully subscribed to Transco. The Leidy South Project would provide 582,400 Dth/d of firm natural gas transportation service from shale producing areas in northern and western Pennsylvania to Transco's customers in the eastern United States. The Federal Energy Regulatory Commission (Commission or FERC) staff's environmental review of the Projects will be presented in a single environmental assessment (EA) because of the interrelatedness of the Projects.

On July 31, 2019 and August 14, 2019, the Commission issued Notices of Application for the FM100 Project and the Leidy South Project, respectively. Among other things, those notices alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's EA for the Projects. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the Projects.

Schedule for Environmental Review

Issuance of EA—February 7, 2020
90-day Federal Authorization Decision Deadline—May 7, 2020

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Projects' progress.

Project Description

National Fuel and Transco are proposing to construct and operate interdependent natural gas infrastructure projects, which are both located entirely within Pennsylvania. The FM100 Project consists of 29.5 miles of new 20-inch-diameter pipeline in McKean and Potter Counties (Line YM58); 1.4 miles of 24-inch-diameter pipeline loop [1] in Potter County (YM224 Loop); 0.4 mile of 12-inch-diameter pipeline in McKean County (Line KL Extension); construction of new Marvindale Compressor Station in McKean County; construction of new Tamarack Compressor Station in Clinton County; construction of the Marvindale Interconnect in McKean County; construction of the Carpenter Hollow over-pressurization protection station in Potter County; abandonment in place of a 44.9-mile-long portion of the existing 12-inch-diameter FM100 Pipeline in Clearfield, Elk, and Potter Counties; abandonment by removal of the existing Costello Compressor Station in Potter County; abandonment by removal of an existing meter station WHP–MS–4317X in Potter County; and installation and abandonment of appurtenances, such as mainline valves and anode beds, associated with the above facilities.

The Leidy South Project consists of 3.5 miles of 42-inch-diameter pipeline loop in Lycoming County (Benton Loop); 2.5 miles of 36-inch-diameter pipeline loop in Clinton County (Hilltop Loop); 6.3 miles of 36-inch-diameter

[1] A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

pipeline loop and related abandonment of a 5.8-mile-long portion of the 23.4-inch-diameter Leidy Line A Pipeline (Hensel Replacement) in Clinton County; modification of existing Compressor Station 605 in Wyoming County; modification of existing Compressor Station 610 in Columbia County; construction of new Compressor Station 607 in Luzerne County; construction of new Compressor Station 620 in Schuylkill County; installation of associated facilities such as mainline valves, communication facilities, and pig[2] launchers and receivers, and other appurtenances.

Background

On March 5, 2019, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed FM100 Project and the Leidy South Project and Request for Comments on Environmental Issues and Notice of Public Scoping Sessions* (NOI). The NOI was issued during the pre-filing review of the Projects in Docket Nos. PF17–10–000 and PF19–1–000 and was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the NOI, the Commission received comments from the U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service, Pennsylvania Department of Agriculture, Pennsylvania Department of Conservation and Natural Resources, Pennsylvania Department of Transportation; 1 state senator; 1 state representative; 3 local agencies; 3 special interest groups; 35 landowners; and 130 individuals.

The majority of issues raised by the commentors are related to the Leidy South Project's proposed Compressor Station 620 in Hegins, Pennsylvania, including impacts on air quality, noise, nearby residences, wildlife, prime farmland and organic farming, visual resources, waterbodies, zoning, future expansion of the facility, emergency response, and safety. Additional issues raised on the Projects include impacts on threatened and endangered species; the Hensel Replacement impact on the Tamarack Swamp Natural Area; landowner requests for removal of the to-be-abandoned Line FM100 from their property; and segmentation of projects under FERC review. All substantive comments will be addressed in the EA.

The U.S. Environmental Protection Agency and the U.S. Army Corps of Engineers are cooperating agencies in the preparation of the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Additional information about the Projects is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP19–491 or CP19–494), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: November 8, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24816 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

[2] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC19–33–000]

Commission Information Collection Activities (FERC–539); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–539 (Gas Pipeline Certificates: Import and Export Related Applications) and submitting the information collection to the Office of Management and Budget (OMB) for review. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below.

DATES: Comments on the collection of information are due December 16, 2019.

ADDRESSES: Comments filed with OMB, identified by the OMB Control No. 1902–0062, should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Office.

A copy of the comments should also be sent to the Commission, in Docket No. IC19–33–000, by either of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION: On September 3, 2019 (84 FR 46005), the Commission published a Notice in the **Federal Register** in Docket No. IC19–33–000 requesting public comments. The Commission received no comments and is noting that in the related submittal to OMB.

Title: FERC–539 (Gas Pipeline Certificates: Import and Export Related Applications).

OMB Control No.: 1902–0062.

Type of Request: Three-year extension of the FERC–539 with no changes to the reporting and recordkeeping requirements.[1]

[1] On 10/29/2019, FERC submitted a request to OMB for an emergency extension. On 10/31/2019, OMB granted a 2-month extension for FERC–539.

Abstract: Section 3 of the Natural Gas Act (NGA) (Pub. L. 75–688) (15 U.S.C. 717–717w) provides, in part, that . . . no person shall export any natural gas from the United States to a foreign country or import any natural gas from a foreign country without first having secured and order from the Commission authorizing it to do so. The 1992 amendments to Section 3 of the NGA concern importation or exportation from/to a nation which has a free trade agreement with the United States, and requires that such importation or exportation: (1) Shall be deemed to be a first sale, *i.e.,* not a sale for a resale, and (2) Shall be deemed to be consistent with the public interest, and applications for such importation or exportation shall be granted without modification or delay.

With the ratification of the North American Free Trade Agreement and the Canadian Free Trade Agreement, the Federal regulatory focus on construction, operation, and siting of import and export facilities increased significantly.

Estimate of Annual Burden.[2] The Commission estimates the annual public reporting burden and cost [3] for the information collection as:

FERC–539, GAS PIPELINE CERTIFICATES: IMPORT & EXPORT RELATED APPLICATIONS

Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours & average cost per response ($)	Total annual burden hours & total annual cost ($)	Cost per respondent ($)
(1)	(2)	(1) × (2) = (3)	(4)	(3) × (4) = (5)	(5) ÷ (1) = (6)
6	2	12	15 hours; $1,200	180 hours; $14,400	$2,400

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: November 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24568 Filed 11–14–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9047–9]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 11/04/2019 10 a.m. ET Through 11/11/2019 10 a.m. ET

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20190270, Final, NMFS, LA, Reduce the Incidental Bycatch and Mortality of Sea Turtles in the Southeastern U.S. Shrimp Fisheries, Review Period Ends: 12/16/2019, Contact: Michael Barnette 727–551–5794

EIS No. 20190271, Final, USACE, CA, Lower Elkhorn Basin Levee Setback Project, Review Period Ends: 12/16/2019, Contact: Tanis Toland 916–557–6717

EIS No. 20190272, Draft Supplement, USACE, AL, Allatoona Lake Water Supply Storage Reallocation Study and Updates to Weiss and Logan Martin Reservoirs Project Water Control Manuals, Comment Period Ends: 12/30/2019, Contact: Jennifer Jacobson 251–690–2724

Dated: November 12, 2019.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2019–24810 Filed 11–14–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843), and interested persons may express their views in writing on the standards enumerated in section 4. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

[2] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. See 5 CFR 1320 for additional information on the definition of information collection burden.

[3] The Commission staff estimates that industry is similarly situated in terms of hourly cost (for wages plus benefits). Based on the Commission's FY (Fiscal Year) 2019 average cost (for wages plus benefits), $80.00/hour is used.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than November 22, 2019.

A. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204. Comments can also be sent electronically to *BOS.SRC.Applications.Comments@bos.frb.org:*

1. *Eastern Bank Corporation, Boston, Massachusetts;* through its subsidiary, Eastern Bank, to retain voting shares of Numerated Growth Technologies, Inc., both of Boston, Massachusetts, and thereby continue to engage in software development and data processing pursuant to section 4(c)(8) of the BHC Act.

B. Federal Reserve Bank of Cleveland (Nadine Wallman, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566. Comments can also be sent electronically to *Comments.applications@clev.frb.org:*

1. *Farmers National Banc Corp, Canfield, Ohio;* to acquire Maple Leaf Financial, Inc., and thereby indirectly acquire Geauga Savings Bank, both of Newbury, Ohio, and thereby operate a savings association pursuant to section 4(c)(8) of the BHC Act.

Board of Governors of the Federal Reserve System, November 8, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–24736 Filed 11–14–19; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[Notice–PBS–2019–10; Docket No. 2019–0002; Sequence No. 24]

Notice of Intent To Prepare an Environmental Impact Statement (EIS) for the Chet Holifield Federal Building in Laguna Niguel, California

AGENCY: Public Buildings Service (PBS), General Services Administration (GSA).

ACTION: Scoping announcement.

SUMMARY: GSA intends to prepare an EIS to analyze the potential impacts from the proposed alternatives to address the long-term housing of all the tenants of the Chet Holifield Federal Building. The building is owned and managed by GSA and is occupied by various federal agency tenants, with the United States Citizenship and Immigration Services (USCIS) serving as the largest tenant.

DATES: The Public Scoping Period will begin on Friday, November 8, 2019. Interested parties are encouraged to provide written comments regarding the scope of the EIS on or before Tuesday, December 10, 2019.

ADDRESSES: Written comments can be submitted by either of the following methods:

- *Email: osmahn.kadri@gsa.gov.*
- *Postal Mail/Commercial Delivery:* ATT: Osmahn Kadri, 50 United Nations Plaza, Room 3345, Mailbox 9, San Francisco, CA 94102.

The views and comments of the public are necessary in helping to determine the scope and content of the environmental analysis.

FOR FURTHER INFORMATION CONTACT: Osmahn A. Kadri, Regional Environmental Quality Advisor/NEPA Project Manager, GSA, at 415–522–3617.

SUPPLEMENTARY INFORMATION:

Background

The Chet Holifield Federal Building was originally built in 1970 by the Aerospace and Systems Group of North American Rockwell Corporation, although it was never occupied by them. The building and site was transferred to the Federal Government for use by federal agencies in March of 1974. As a result of the age and current condition of the Chet Holifield Federal Building, there are a number of issues with the building to be addressed, including abatement of asbestos containing materials and enhancement of the building's structural system.

The development of this project necessitates an Environmental Impact Statement (EIS) under the National Environmental Policy Act (NEPA) and the GSA Public Buildings Service NEPA Desk Guide as well as Council on Environmental Quality Laws, Regulations, and Executive Orders.

Alternatives

The EIS will consider two ''action'' alternatives and one ''no action'' alternative. One action alternative consists of relocation of current tenants into lease space primarily throughout the Orange County, California market. Some tenants may be relocated outside of Orange County. The existing Chet Holifield Federal Building and surrounding government property would be turned over to the GSA Real Property Utilization Disposal Division.

The other action alternative consists of construction of a new federal office building south of the existing Chet Holifield Federal Building for the USCIS and relocating all other tenants into lease space primarily within the Orange County market. The existing building and the remainder of the property not retained for construction of the new Federal Office Building would be turned over to the GSA Real Property Utilization Disposal Division.

The ''no action'' alternative assumes that the current issues with the Chet Holifield Federal Building would not be addressed and that operations would continue under current conditions.

Dated: November 7, 2019.

Jared Bradley,

Director, Portfolio Management Division, Pacific Rim Region, Public Buildings Service.

[FR Doc. 2019–24818 Filed 11–14–19; 8:45 am]

BILLING CODE 6820–YF–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0310; Docket No. 2019–0001; Sequence No. 8]

Submission for OMB Review; Nondiscrimination in Federal Financial Assistance Programs, GSA Form 3702

AGENCY: Office of Civil Rights, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an existing information collection requirement regarding OMB Control No: 3090–0310; Nondiscrimination in Federal Financial Assistance Programs, GSA 3702. This information is needed to facilitate nondiscrimination in GSA's Federal Financial Assistance Programs, consistent with Federal civil rights laws and regulations that apply to recipients of Federal financial assistance.

DATES: *Submit comments on or before:* December 16, 2019.

FOR FURTHER INFORMATION CONTACT: Evelyn Britton, Branch Manager, External Programs Branch, Office of Civil Rights, at telephone 202–501–0767 or via email to *evelyn.britton@gsa.gov.*

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the

OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–0310, Nondiscrimination in Federal Financial Assistance Programs, GSA 3702''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–0310, Nondiscrimination in Federal Financial Assistance Programs, GSA 3702'' on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 3090–0228, Nondiscrimination in Federal Financial Assistance Programs, GSA 3702.

Instructions: Please submit comments only and cite Information Collection 3090–0310, Nondiscrimination in Federal Financial Assistance Programs, GSA 3702, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA has mission responsibilities related to monitoring and enforcing compliance with Federal civil rights laws and regulations that apply to Federal financial assistance programs administered by GSA. Specifically, those laws provide that no person on the ground of race, color, national origin, disability, sex or age shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program in connection with which Federal financial assistance is extended under laws administered in whole, or in part, by GSA.

These mission responsibilities generate the requirement to request and obtain certain data from recipients of Federal surplus property for the purpose of determining compliance, such as the number of individuals, based on race and ethnic origin, of the recipient's eligible and actual serviced population; race and national origin of those denied participation in the recipient's program(s); non-English languages encountered by the recipient's program(s) and how the recipient is addressing meaningful access for individuals that are Limited English Proficient; whether there has been complaints or lawsuits filed against the recipient based on prohibited discrimination and whether there has been any findings; and whether the recipient's facilities are accessible to qualified individuals with disabilities.

B. Annual Reporting Burden

Respondents: *1,200.*
Responses Per Respondent: *1.*
Total Responses: *1,200.*
Hours Per Response: *2.*
Total Burden Hours: *2400.*

C. Public Comments

A notice published in the **Federal Register** at 84 FR 44620 on August 26, 2019. No comments were received.

Public comments are particularly invited on: Whether this collection of information will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0310, Nondiscrimination in Federal Financial Assistance Programs, GSA 3702, in all correspondence.

Dated: November 7, 2019.

David A. Shive,

Chief Information Officer.

[FR Doc. 2019–24817 Filed 11–14–19; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–19BIW]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Evaluation of the DP18–1801 Healthy Schools Program to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 25, 2019 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Evaluation of the DP18–1801 Healthy Schools Program—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention's (CDC) School Health Branch (SHB) requests a three-year OMB

approval to conduct a new information collection entitled Evaluation of the DP18–1801 Healthy Schools Program. The DP18–1801 Healthy Schools Program builds upon previous CDC efforts designed to enhance the capacity of state education agencies (SEAs) to adopt and implement evidence-based policies, practices, and programs that support health among the nation's youth. The purpose of the DP18–1801 Healthy Schools Program is to: (1) Increase the number of students who consume nutritious food and beverages (*i.e.,* those aligned with the *Dietary Guidelines for Americans*); (2) increase the number of students who participate in daily physical education and physical activity; and (3) increase the number of students who can effectively manage their chronic health conditions. The evaluation approach is a multisite, embedded case study design, consisting of both process and outcome components, focusing on three 1801 state grantees and a subset of their targeted LEAs and schools. The process component will assess implementation of strategies and activities at the state, local, and school levels and their integration across levels; fidelity of implementation; implementation facilitators and barriers; and contributions of national and state level TA towards program achievements. Three primary data collection methods will be used: (1) Key informant interviews (KII) conducted during in-person site visits or by phone, (2) Web-based surveys, and (3) review of secondary data sources. CDC is requesting approval for an estimated 265 annual burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
SEA staff	Web-Survey	3	1	75/60
	Key-Informant Interview	9	1	75/60
LEA staff	Web-Survey	30	1	75/60
	Key-Informant Interview	12	1	75/60
School staff	Web-Survey	210	1	75/60
	Key-Informant Interview	54	1	75/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–24728 Filed 11–14–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Maternal, Infant, and Early Childhood Home Visiting Program Form 2: Grantee Performance Measures (OMB #0970–0500)

AGENCY: Office of Child Care; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the ACF-Tribal Maternal, Infant, and Early Childhood Home Visiting (Tribal MIECHV) Program Form 2: Grantee Performance Measures (OMB #0970–0500; Expiration date 8/31/2020). There are no changes requested to the form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) authorizes the Secretary of HHS (in Section 511(h)(2)(A)) to award grants to Indian tribes (or a consortium of Indian tribes), tribal organizations, or urban Indian organizations to conduct an early childhood home visiting program. The legislation set aside 3 percent of the total MIECHV program appropriation for grants to tribal entities. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to states and jurisdictions and include conducting a needs assessment and establishing quantifiable, measurable benchmarks.

The ACF, Office of Child Care, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, awards grants for the Tribal MIECHV Program. The Tribal MIECHV grant awards support 5-year cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally relevant, evidence-based home visiting programs in at-risk tribal communities; collect and report on performance measures; and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

Specifically, the MIECHV legislation requires that State and Tribal MIECHV grantees collect performance data to measure improvements for eligible families in six specified areas (referred to as ''benchmark areas'') that encompass the major goals for the program. These include:

1. Improved maternal and newborn health;
2. Prevention of child injuries, child abuse, neglect, or maltreatment, and reduction in emergency department visits;
3. Improvement in school readiness and achievement;
4. Reduction in crime or domestic violence;
5. Improvement in family economic self-sufficiency; and
6. Improvement in the coordination and referrals for other community resources and supports.

Tribal MIECHV grantees are required to propose a plan for meeting the benchmark requirements specified in the legislation and must report on

improvement on constructs under each benchmark area. The Tribal Home Visiting (HV) Form 2 provides a template for Tribal MIECHV grantees to report data on their progress in improving performance under the six benchmark areas, as stipulated in the legislation.

ACF will continue to use Tribal HV Form 2 to:

- Track and improve the quality of benchmark measures data submitted by the Tribal grantees;
- Improve program monitoring and oversight;
- Improve rigorous data analyses that help to assess the effectiveness of the programs and enable ACF to better monitor projects; and
- Ensure adequate and timely reporting of program data to relevant federal agencies and stakeholders including Congress and members of the public.

Respondents: Tribal MIECHV Program Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal MIECHV Form 2	25	1	500	12,500

Estimated Total Annual Burden Hours: 12,500.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Public Law 115–123, Section 511(h)(2)(A) of Title V of the Social Security Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–24797 Filed 11–14–19; 8:45 am]

BILLING CODE 4184–77–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2544]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Current Good Manufacturing Practice Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by December 16, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0073. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Current Good Manufacturing Practice Quality System Regulation—21 CFR Part 820

OMB Control Number 0910–0073—Extension

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device, but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice (CGMP), as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the FD&C Act.

The CGMP quality system (QS) regulation implementing authority provided by this statutory provision is found under part 820 (21 CFR part 820) and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. The authority for this regulation is covered under sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, and 803 of the FD&C Act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, and 383). The CGMP/QS regulation includes requirements for purchasing and service controls, clarifies recordkeeping requirements for device failure and complaint investigations, clarifies requirements for verifying/validating production processes and process or product changes, and clarifies requirements for product acceptance activities, quality data evaluations, and corrections of nonconforming product/quality problems.

Requirements are compatible with specifications in the international standards ''ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.'' The CGMP/QS information collections will assist FDA inspections of manufacturers for compliance with QS requirements encompassing design, production, installation, and servicing processes.

Section 820.20(a) through (e) requires management with executive responsibility to establish, maintain, and/or review the following topics: (1) The quality policy, (2) the organizational structure, (3) the quality plan, and (4) the quality system procedures of the organization. Section 820.22 requires the conduct and documentation of QS audits and reaudits. Section 820.25(b) requires the establishment of procedures to identify training needs and documentation of such training.

Section 820.30(a)(1) and (b) through (j) requires, in respective order, the establishment, maintenance, and/or documentation of the following topics: (1) Procedures to control design of class III and class II devices and certain class I devices as listed therein; (2) plans for design and development activities and updates; (3) procedures identifying, documenting, and approving design input requirements; (4) procedures defining design output, including acceptance criteria, and documentation of approved records; (5) procedures for formal review of design results and documentation of results in the design history file (DHF); (6) procedures for verifying device design and documentation of results and approvals in the DHF; (7) procedures for validating device design, including documentation of results in the DHF; (8) procedures for translating device design into production specifications; (9) procedures for documenting, verifying, and validating approved design changes before implementation of changes; and (10) the records and references constituting the DHF for each type of device.

Section 820.40 requires manufacturers to establish and maintain procedures controlling approval and distribution of required documents and document changes. Section 820.40(a) and (b) requires the establishment and maintenance of procedures for the review, approval, issuance, and documentation of required records (documents) and changes to those records.

Section 820.50(a) and (b) requires the establishment and maintenance of procedures and requirements to ensure service and product quality, records of acceptable suppliers, and purchasing data describing specified requirements for products and services.

Sections 820.60 and 820.65 require, respectively, the establishment and maintenance of procedures for identifying all products from receipt to distribution and for using control numbers to track surgical implants and life-sustaining or supporting devices and their components.

Section 820.70(a) through (e), (g)(1) through (3), (h), and (i) requires the establishment, maintenance, and/or documentation of the following topics: (1) Process control procedures; (2) procedures for verifying or validating changes to specification, method, process, or procedure; (3) procedures to control environmental conditions and inspection result records; (4) requirements for personnel hygiene; (5) procedures for preventing contamination of equipment and products; (6) equipment adjustment, cleaning, and maintenance schedules; (7) equipment inspection records; (8) equipment tolerance postings, procedures for utilizing manufacturing materials expected to have an adverse effect on product quality; and (9) validation protocols and validation records for computer software and software changes.

Sections 820.72(a), (b)(1) and (2), and 820.75(a) through (c) require, respectively, the establishment, maintenance, and/or documentation of the following topics: (1) Equipment calibration and inspection procedures; (2) national, international, or in-house calibration standards; (3) records that identify calibrated equipment and next calibration dates; (4) validation procedures and validation results for processes not verifiable by inspections and tests; (5) procedures for keeping validated processes within specified limits; (6) records for monitoring and controlling validated processes; and (7) records of the results of revalidation where necessitated by process changes or deviations.

Sections 820.80(a) through (e) and 820.86, respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Procedures for incoming acceptance by inspection, test, or other verification; (2) procedures for ensuring that in-process products meet specified requirements and the control of product until inspection and tests are completed; (3) procedures for, and records that show, incoming acceptance or rejection is conducted by inspections, tests, or other verifications; (4) procedures for, and records that show, finished devices meet acceptance criteria and are not distributed until device master record (DMR) activities are completed; (5) records in the device history record (DHR) showing acceptance dates, results, and equipment used; and (6) the acceptance/rejection identification of products from receipt to installation and servicing.

Sections 820.90(a), (b)(1) and (2), and 820.100 require, respectively, the establishment, maintenance and/or documentation of the following topics: (1) Procedures for identifying, recording, evaluating, and disposing of nonconforming product; (2) procedures for reviewing and recording concessions made for, and disposition of, nonconforming product; (3) procedures for reworking products, evaluating possible adverse rework effect and recording results in the DHR; (4) procedures and requirements for corrective and preventive actions, including analysis, investigation, identification and review of data, records, causes, and results; and (5) records for all corrective and preventive action activities.

Section 820.100(a)(1) through (7) states that procedures and requirements shall be established and maintained for corrective/preventive actions, including the following: (1) Analysis of data from process, work, quality, servicing records, investigation of nonconformance causes; (2) identification of corrections and their effectiveness; (3) recording of changes made; and (4) appropriate distribution and managerial review of corrective and preventive action information. Section 820.120 states that manufacturers shall establish/maintain procedures to control labeling storage/application, examination/release for storage and use, and to document those procedures.

Sections 820.120(b) and (d), 820.130, 820.140, 820.150(a) and (b), 820.160(a) and (b), and 820.170(a) and (b), respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Procedures for controlling and recording the storage, examination, release, and use of labeling; (2) the filing of labels/labeling used in the DHR; (3) procedures for controlling product storage areas and receipt/dispatch authorizations; (4) procedures controlling the release of products for distribution; (5) distribution records that identify consignee, product, date, and control numbers; and (6) instructions, inspection and test procedures that are made available, and the recording of results for devices requiring installation.

Sections 820.180(b) and (c), 820.181(a) through (e), 820.184(a) through (f), and 820.186 require, respectively, the maintenance of records that are: (1) Retained at prescribed site(s), made readily available and accessible to FDA, and retained for the device's life expectancy or for 2 years; (2) contained or referenced in a DMR consisting of device, process, quality assurance, packaging and labeling, and

installation, maintenance, and servicing specifications and procedures; (3) contained in a DHR and demonstrate the manufacture of each unit, lot, or batch of product in conformance with DMR and regulatory requirements include manufacturing and distribution dates, quantities, acceptance documents, labels and labeling, and control numbers; and (4) contained in a quality system record, consisting of references, documents, procedures, and activities not specific to particular devices.

Sections 820.198(a) through (g) and 820.200(a) through (d), respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Complaint files and procedures for receiving, reviewing, and evaluating complaints; (2) complaint investigation records identifying the device, complainant, and relationship of the device to the incident; (3) complaint records that are reasonably accessible to the manufacturing site or at prescribed sites; (4) procedures for performing and verifying that device servicing requirements are met and that service reports involving complaints are processed as complaints; and (5) service reports that record the device, service activity, and test and inspection data.

Section 820.250 requires the establishment and maintenance of procedures to identify valid statistical techniques necessary to verify process and product acceptability; and sampling plans, when used, which are written and based on valid statistical rationale; and procedures for ensuring adequate sampling methods.

The CGMP/QS regulation added design and purchasing controls, modified previous critical device requirements, revised previous validation and other requirements, and harmonized device CGMP requirements with QS specifications in the international standard ''ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.'' The rule does not apply to manufacturers of components or parts of finished devices, or to manufacturers of human blood and blood components subject to 21 CFR part 606. With respect to devices classified in class I, design control requirements apply only to class I devices listed in § 820.30(a)(2) of the regulation. The rule imposes burden upon: (1) Finished device manufacturer firms, which are subject to all recordkeeping requirements; (2) finished device contract manufacturers, specification developers; and (3) re-packer, re-labelers, and contract sterilizer firms, which are subject only to requirements applicable to their activities. In addition, remanufacturers of hospital single-use devices are now considered to have the same requirements as manufacturers in regard to the regulation.

The establishment, maintenance, and/or documentation of procedures, records, and data required by the regulation assists FDA in determining whether firms are in compliance with CGMP requirements, which are intended to ensure that devices meet their design, production, labeling, installation, and servicing specifications and, thus are safe, effective, and suitable for their intended purpose. In particular, compliance with CGMP design control requirements should decrease the number of design-related device failures that have resulted in deaths and serious injuries.

The CGMP/QS regulation applies to approximately 27,074 respondents. This estimate is based on a query of the Agency's registration and listing database. Respondents to this information collection have no reporting activities, but must make required records available for review or copying during FDA inspection. Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to Quality Policy (§ 820.20(a)), Document Control (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to subpart C, Design Controls. The PRA burden placed on the 27,074 establishments is an average burden.

In the **Federal Register** of July 31, 2019 (84 FR 37317), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Quality policy–820.20(a)	27,074	1	27,074	7	189,518
Organization–820.20(b)	27,074	1	27,074	4	108,296
Management review–820.20(c)	27,074	1	27,074	6	162,444
Quality planning–820.20(d)	27,074	1	27,074	10	270,740
Quality system procedures–820.20(e)	27,074	1	27,074	10	270,740
Quality audit–820.22	27,074	1	27,074	33	893,442
Training–820.25(b)	27,074	1	27,074	13	351,962
Design procedures–820.30(a)(1)	27,074	1	27,074	2	54,148
Design and development planning–820.30(b)	27,074	1	27,074	6	162,444
Design input–820.30(c)	27,074	1	27,074	2	54,148
Design output–820.30(d)	27,074	1	27,074	2	54,148
Design review–820.30(e)	27,074	1	27,074	23	622,702
Design verification–820.30(f)	27,074	1	27,074	37	1,001,738
Design validation–820.30(g)	27,074	1	27,074	37	1,001,738
Design transfer–820.30(h)	27,074	1	27,074	3	81,222
Design changes–820.30(i)	27,074	1	27,074	17	460,258
Design history file–820.30(j)	27,074	1	27,074	3	81,222
Document controls–820.40	27,074	1	27,074	9	243,666
Documentation approval and distribution and document changes–820.40(a) and (b)	27,074	1	27,074	2	54,148
Purchasing controls–820.50(a)	27,074	1	27,074	22	595,628
Purchasing data–820.50(b)	27,074	1	27,074	6	162,444
Identification–820.60	27,074	1	27,074	1	27,074
Traceability–820.65	27,074	1	27,074	1	27,074
Production and process controls–820.70(a)	27,074	1	27,074	2	54,148

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Production and process changes and environmental control–820.70(b) and (c)	27,074	1	27,074	2	54,148
Personnel–820.70(d)	27,074	1	27,074	3	81,222
Contamination control–820.70(e)	27,074	1	27,074	2	54,148
Equipment maintenance schedule, inspection, and adjustment–820.70(g)(1)–(3)	27,074	1	27,074	1	27,074
Manufacturing material–820.70(h)	27,074	1	27,074	2	54,148
Automated processes–820.70(i)	27,074	1	27,074	8	216,592
Control of inspection, measuring, and test equipment–820.72(a)	27,074	1	27,074	5	135,370
Calibration procedures, standards, and records–820.72(b)(1)–(2)	27,074	1	27,074	1	27,074
Process validation–820.75(a)	27,074	1	27,074	3	81,222
Validated process parameters, monitoring, control methods, and data–820.75(b)	27,074	1	27,074	1	27,074
Revalidation–820.75(c)	27,074	1	27,074	1	27,074
Acceptance activities–820.80(a)–(e)	27,074	1	27,074	5	135,370
Acceptance status–820.86	27,074	1	27,074	1	27,074
Control of nonconforming product–820.90(a)	27,074	1	27,074	5	135,370
Nonconforming product review/disposition procedures and rework procedures–820.90(b)(1)–(2)	27,074	1	27,074	5	135,370
Procedures for corrective/preventive actions–820.100(a)(1)–(7)	27,074	1	27,074	12	324,888
Corrective/preventive activities–820.100(b)	27,074	1	27,074	1	27,074
Labeling procedures–820.120(b)	27,074	1	27,074	1	27,074
Labeling documentation–820.120(d)	27,074	1	27,074	1	27,074
Device packaging–820.130	27,074	1	27,074	1	27,074
Handling–820.140	27,074	1	27,074	6	162,444
Storage–820.150(a) and (b)	27,074	1	27,074	6	162,444
Distribution procedures and records–820.160(a) and (b)	27,074	1	27,074	1	27,074
Installation–820.170	27,074	1	27,074	2	54,148
Record retention period–820.180(b) and (c)	27,074	1	27,074	2	54,148
Device master record–820.181	27,074	1	27,074	1	27,074
Device history record–820.184	27,074	1	27,074	1	27,074
Quality system record–820.186	27,074	1	27,074	1	27,074
Complaint files–820.198(a)–(g)	27,074	1	27,074	5	135,370
Servicing procedures and reports–820.200(a) and (d)	27,074	1	27,074	3	81,222
Statistical techniques procedures and sampling plans–820.250	27,074	1	27,074	1	27,074
Total					9,421,752

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 812,928 hours. We attribute this adjustment to an increase in the number of respondents.

Dated: November 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24805 Filed 11–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0117]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 16, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0670. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601

Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims OMB Control Number 0910–0670—Extension

This information collection request supports recommendations found in Agency guidance. The document entitled, ''Guidance for Industry; Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims,'' available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hypertension-indication-drug-labeling-cardiovascular-outcome-claims,* encourages the submission of supplemental labeling and is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension, and to provide common labeling for antihypertensive drugs except where differences are clearly supported by clinical data.

With few exceptions, current labeling for antihypertensive drugs includes only the information that these drugs are indicated to reduce blood pressure; the labeling does not include information on the clinical benefits related to cardiovascular outcomes expected from such blood pressure reduction. However, blood pressure control is well established as beneficial in preventing serious cardiovascular events, and inadequate treatment of hypertension is acknowledged as a significant public health problem. We believe that the appropriate use of these drugs can be encouraged by making the connection between lower blood pressure and improved cardiovascular outcomes more explicit in labeling.

As discussed in the guidance, we therefore recommend the following information collection:

1. Section IV.C of the guidance requests that the CLINICAL STUDIES section of the Full Prescribing Information of the labeling should include a summary of placebo or active-controlled trials showing evidence of the specific drug's effectiveness in lowering blood pressure. If trials demonstrating cardiovascular outcome benefits exist, those trials also should be summarized in this section. Table 1 in section V of the guidance contains the specific drugs for which FDA has concluded that such trials exist. If there are no cardiovascular outcome data to cite, one of the following two paragraphs should appear:

- ''There are no trials of [DRUGNAME] or members of the [name of pharmacologic class] pharmacologic class demonstrating reductions in cardiovascular risk in patients with hypertension,'' or
- ''There are no trials of [DRUGNAME] demonstrating reductions in cardiovascular risk in patients with hypertension, but at least one pharmacologically similar drug has demonstrated such benefits.''

In the latter case, the applicant's submission generally should refer to table 1 in section V of the guidance. If the applicant believes that table 1 is incomplete, it should submit the clinical evidence for the additional information to Docket No. FDA–2008–D–0150. The labeling submission should reference the submission to the docket. We estimate that no more than one submission to the docket will be made annually from one company, and that each submission will take approximately 10 hours to prepare and submit. Recommendations for the CLINICAL STUDIES section of the Full Prescribing Information of the labeling are covered by FDA regulations at §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) and require such labeling. The information collection associated with these regulations is approved under OMB control number 0910–0572.

2. Section VI.B of the guidance requests that the format of the cardiovascular outcome claim submitted to FDA in a prior approval supplement include the following information:

- A statement that the submission is a cardiovascular outcome claim supplement, with reference to the guidance and related Docket No. FDA–2008–D–0150.
- Applicable FDA forms (*e.g.,* 356h, 3397).
- Detailed table of contents.
- Revised labeling to include:
  - Draft revised labeling conforming to the requirements in §§ 201.56 and 201.57, and
  - Marked-up copy of the latest approved labeling, showing all additions and deletions, with annotations of where supporting data (if applicable) are located in the submission.

We estimate that on average, 4 cardiovascular outcome claim supplements will be submitted annually from 4 different companies, and that each supplement will take approximately 20 hours to prepare and submit. The guidance also recommends that other labeling changes (*e.g.,* the addition of adverse event data) should be minimized and provided in separate supplements, and that the revision of labeling to conform to §§ 201.56 and 201.57 may require substantial revision to the ADVERSE REACTIONS or other labeling sections.

3. Section VI.C of the guidance states that applicants are encouraged to include the following statement in the drug's promotional materials:

- ''[DRUGNAME] reduces blood pressure, which reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Controlling high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals.''

The inclusion of this statement in the promotional materials for the drug is exempt from OMB review under 5 CFR 1320.3(c)(2).

In the **Federal Register** of July 16, 2019 (84 FR 33952), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We therefore estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Submission to Docket No. FDA–2008–D–0150	1	1	1	10	10
Cardiovascular Outcome Claim Supplement Submission	4	1	4	20	80

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Total					90

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate for the information collection reflects an overall increase of burden. This increase corresponds to an increase in submissions we have received over the last few years.

Dated: November 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24780 Filed 11–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0350]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Tobacco Retailers on Tobacco Retailer Training Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 16, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0745. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Tobacco Retailers on Tobacco Retailer Training Programs

OMB Control Number 0910–0745—Extension

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) does not require retailers to implement retailer training programs. However, the statute does provide for lesser civil money penalties for violations of access, advertising, and promotion restrictions of regulations issued under section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)), as amended by the Tobacco Control Act, for retailers who have implemented a training program that complies with standards developed by FDA for such programs. FDA intends to issue regulations establishing standards for approved retailer training programs. In the interim, the guidance is intended to assist tobacco retailers in implementing effective training programs for employees.

The guidance discusses recommended elements that should be covered in a training program, such as: (1) Federal laws restricting the access to, and the advertising and promotion of, cigarettes, smokeless, and covered tobacco products; (2) the health and economic effects of tobacco use, especially when the tobacco use begins at a young age; (3) written company policies against sales to minors and other restrictions on the access to, and the advertising and promotion of, tobacco products; (4) identification of the tobacco products sold in the retail establishment that are subject to the Federal laws prohibiting their sale to persons under the age of 18; (5) age verification methods; (6) practical guidelines for refusing sales; and (7) testing to ensure that employees have the required knowledge. The guidance recommends that retailers require current and new employees to take a written test prior to selling tobacco products and that refresher training be provided at least annually and more frequently as needed. The guidance recommends that retailers maintain certain written records documenting that all individual employees have been trained and that retailers retain these records for 4 years in order to be able to provide evidence of a training program during the 48-month time period covered by the civil money penalty schedules in section 103(q)(2)(A) of the Tobacco Control Act.

The guidance also recommends that retailers implement certain hiring and management practices as part of an effective retailer training program. The guidance suggests that applicants and current employees be notified both verbally and in writing of the importance of complying with laws prohibiting the sales of tobacco products to persons under the age of 18. In addition, FDA recommends that retailers implement an internal compliance check program and document the procedures and corrective actions for the program.

In the **Federal Register** of June 17, 2019 (84 FR 28059), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related.

The comment suggested that FDA should adjust the burden calculation for two areas, develop training programs and review and updating training programs. The comment suggested that it would reasonably take 1000 hours to develop a training program. FDA disagrees with this comment and does not intend to adjust the burden calculations for these areas. FDA has not made significant changes to this guidance and expects that many retailer training programs already meet the elements in the guidance, some retailers would update their training program to meet the elements in the guidance, and a smaller number of other retailers would develop a training program for the first time. FDA has not received any comments from affected retailers regarding the time needed to develop retailer training programs, or that the burden calculation was insufficient. Additionally, FDA has provided several resources, such as webinars and

downloadable materials through FDA's ''This is Our Watch'' Program, to assist retailers in complying with the requirements under the law. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Develop training program	273,900	1	273,900	16	4,382,400
Develop written policy against sales to minors and employee acknowledgement	273,900	1	273,900	1	273,900
Develop internal compliance check program	273,900	1	273,900	8	2,191,200
Total					6,847,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Training program	273,900	4	1,095,600	0.25 (15 minutes)	273,900
Written policy against sales to minors and employee acknowledgement.	273,900	4	1,095,600	0.10 (6 minutes) ..	109,560
Internal compliance check program	273,900	2	547,800	0.5 (30 minutes) ..	273,900
Total					657,360

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents in tables 1 and 2 is based on data reported to the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration. According to the fiscal year 2009 Annual Synar Report, there are 372,677 total retail tobacco outlets in the 50 States, District of Columbia, and 8 U.S. territories that are accessible to youth (meaning that there is no State law restricting access to these outlets to individuals older than age 18). Inflating this number by about 10 percent to account for outlets in States that sell tobacco but are, by law, inaccessible to minors, results in an estimated total number of tobacco outlets of 410,000. We assume that 75 percent of tobacco retailers already have some sort of training program for age and identification verification. We expect that some of those retailer training programs already meet the elements in the guidance, some retailers would update their training program to meet the elements in the guidance, and other retailers would develop a training program for the first time. Thus, we estimate that two-thirds of tobacco retailers would develop a training program that meets the elements in the guidance (66% of 410,000 = 270,600).

FDA estimates that the total burden for this collection will be 7,504,860 hours (6,847,500 reporting + 657,360 recordkeeping).

We also estimate that there are approximately 5,000 to 10,000 vape shops; we assume that 66 percent of them, or 3,300 (66% × 5,000) of the low estimate, currently engage in retailing activities (Ref. 1).

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

II. Reference

The following reference is on display with the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is not available electronically at *https://www.regulations.gov* as this reference is copyright protected. It may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Burke, D., ''Trends & Insights in the Nicotine Delivery Category.'' Management Science Associates, Inc. Presentation at NATO Show, April 23, 2015.

Dated: November 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24785 Filed 11–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Q-Submission Program for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 16, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0756. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Q-Submission Program for Medical Devices

OMB Control Number 0910–0756—Extension

The guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (*https://www.fda.gov/media/114034/download*) provides an overview of the mechanisms available to submitters through which they can request feedback from or a meeting with FDA regarding certain potential or planned medical device submissions reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding certain types of Q-Submissions, such as Pre-Submissions, Submission Issue Requests, Study Risk Determinations, Informational Meetings, and other Q-Submissions Types and other uses of the Q-Submission Program.

For clarity and consistency with the guidance that describes the program, we are requesting that the title of the information collection request, OMB control number 0910–0756, be changed to ''Q-Submission Program for Medical Devices.''

In the **Federal Register** of August 13, 2019 (84 FR 40069), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CDRH	3,502	1	3,502	137	479,774
CBER	91	1	91	137	12,467
Total					492,241

[1] There are no capital costs or operating and maintenance cost associated with this of information.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 3,593 submissions is based on experienced recent trends. FDA's administrative and technical staffs, who are familiar with Q-Submissions, estimate that an average of 137 hours is required to prepare a Q-Submission.

Our estimated burden for the information collection reflects an overall increase of 143,713 hours. We attribute this adjustment to an increase in the number of submissions we received based on FY18 data.

Dated: November 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24803 Filed 11–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0796]

Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications on Medical Devices and Radiation-Emitting Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on communication studies involving medical devices and radiation-emitting products regulated by FDA. This information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the Agency's mission to protect the public health.

DATES: Submit either electronic or written comments on the collection of information by January 14, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 14, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 14, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0796 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications on Medical Devices and Radiation-Emitting Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Testing Communications on Medical Devices and Radiation-Emitting Products

OMB Control Number 0910–0678—Extension

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of regulated medical devices and radiation-emitting products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. Improving communications about medical devices and radiation emitting products will involve many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about medical device and radiation-emitting product use. Knowledge of consumer and health care professional decision-making processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using medical devices and radiation-emitting products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the

messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

Annually, FDA projects conducting about 30 studies using a variety of research methods and lasting an average of 0.17 hours each (varying from 0.08 to 1.5 hours). FDA estimates the burden of this collection of information based on prior experience with the various types of data collection methods described earlier. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interviews	360	1	360	0.75 (45 minutes)	270
General Public Focus Group Interviews	144	1	144	1.5	216
Intercept Interviews: Central Location	200	1	200	0.25 (15 minutes)	50
Intercept Interviews: Telephone	4,000	1	4,000	0.08 (5 minutes)	320
Self-Administered Surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper Reviews	400	1	400	0.5 (30 minutes)	200
Omnibus Surveys	1,200	1	1,200	0.17 (10 minutes)	204
Total (General Public)	8,704		8,702		1,860
Physician Focus Group Interviews	144	1	144	1.5	216
Total (Physician)	144				216
Total (Overall)	8,848				2,076

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: November 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24804 Filed 11–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

Date: January 12–14, 2020.

Time: 6:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lorna W. Role, Ph.D., Scientific Director, Division of Intramural Research, National Institute of Neurological Disorders and Stroke, 35A Convent Drive, MSC 3716, Bethesda, MD 20892, *lorna.role@nih.gov.*

Name of Committee: Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

Date: March 22–24, 2020.

Time: 6:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lorna W. Role, Ph.D., Scientific Director, Division of Intramural Research, National Institute of Neurological Disorders and Stroke, 35A Convent Drive, MSC 3716, Bethesda, MD 20892, *lorna.role@nih.gov.*

Name of Committee: Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

Date: June 21–23, 2020.

Time: 6:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lorna W. Role, Ph.D., Scientific Director, Division of Intramural Research, National Institute of Neurological Disorders and Stroke, 35A Convent Drive, MSC 3716, Bethesda, MD 20892, *lorna.role@nih.gov.*

Name of Committee: Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

Date: October 4–6, 2020.

Time: 6:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lorna W. Role, Ph.D., Scientific Director, Division of Intramural Research, National Institute of Neurological Disorders and Stroke, 35A Convent Drive, MSC 3716, Bethesda, MD 20892, *lorna.role@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: November 7, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24775 Filed 11–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of NIGMS Sponsored Programs Administration Development (SPAD) Grant Applications.

Date: November 25, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Circle Hotel, 1500 New Hampshire Ave. NW, Washington, DC 20036.

Contact Person: Lisa A. Dunbar, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, (301) 594–2849, *dunbarl@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: November 7, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24774 Filed 11–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute On Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; HIV and CVS.

Date: November 18, 2019.

Time: 2:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Anita H. Undale, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 827–7428, *anita.undale@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Aging Special Emphasis Panel; Second Stage Review.

Date: December 3–4, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Kimberly Firth, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892, (301) 402–7702, *firthkm@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: November 8, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24771 Filed 11–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Review of R35 Research Program Award.

Date: November 18–19, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Long Beach, 500 E 1st St., Long Beach, CA 90802.

Contact Person: Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute of Neurological Disorders and Stroke, Bethesda, MD 20892, 301–827–9087, *mooremar@mail.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Blueprint Neurotherapeutics Network (BPN): Small Molecule Drug Discovery and Development for Disorders of the Nervous System''.

Date: November 21, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street NW, Washington, DC 20037.

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Room 3205, MSC 9529, Bethesda, MD 20892, (301) 496–9223, *joel.saydoff@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; VCID R01 Review.

Date: November 25, 2019.

Time: 11:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).
Contact Person: Mir Ahamed Hossain, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–9223, *mirahamed.hossain@nih.gov*.
(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: November 7, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24778 Filed 11–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Human Genetic Cell Repository Review.
Date: December 5, 2019.
Time: 1:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN12N, 45 Center Drive, Bethesda, MD 20982 (Telephone Conference Call).
Contact Person: Lisa A. Dunbar, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, (301) 594–2849, *dunbarl@mail.nih.gov*.
(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: November 8, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24772 Filed 11–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Atopic Dermatitis Research Network Leadership Center (UM1 Clinical Trial Required).
Date: December 5, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.
Contact Person: Louis A. Rosenthal, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Rm 3G42B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892–9834, (240) 669–5070, *rosenthalla@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Atopic Dermatitis Research Network—Clinical Research Centers (U01 Clinical Trial Optional).
Date: December 5–6, 2019.
Time: 12:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.
Contact Person: Louis A. Rosenthal, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Rm 3G42B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892–9834, (240) 669–5070, *rosenthalla@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HIV/AIDS Clinical Trials Networks Laboratory Centers (UM1 Clinical Trial Required).
Date: December 9–10, 2019.
Time: 9:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892.
Contact Person: Steven F. Santos, Ph.D., Scientific Review Officer, AIDS Research Review Branch, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, NIAID, 5601 Fishers Lane, Room 3G33, Rockville, MD 20852, 301–761–7049, *steven.santos@nih.gov*.
(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 8, 2019.

Tyeshia M. Roberson,

Program Analyst. Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24773 Filed 11–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Environmental Health Sciences Special Emphasis Panel, which was published in the **Federal Register** on October 30, 2019, 84 FR 58164.

The National Institute of Environmental Health Sciences Special Emphasis Panel Meeting: E-Learning for Hazmat and Emergency Response, is being amended due to a change in the meeting time. This one day meeting will be held on November 12th, 2019 at 1:00 p.m. and will end at 4:00 p.m. This meeting is closed to the public.

Dated: November 7, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24777 Filed 11–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Dissemination and Implementation Research in Health.

Date: November 22, 2019.

Time: 2:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rock Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Gabriel B. Fosu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435–3562, *fosug@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Pulmonary Diseases.

Date: December 2–3, 2019.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bradley Nuss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC7814, Bethesda, MD 20892, 301–451–8754, *nussb@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research.

Date: December 4–5, 2019.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shalanda A. Bynum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, 301–755–4355, *bynumsa@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Chronic Diseases and Epidemiology.

Date: December 4, 2019.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Chittari V. Shivakumar, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–408–9098, *chittari.shivakumar@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery and Delivery.

Date: December 4, 2019.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert C. Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892, 301–435–3009, *elliotro@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Privacy Medicine.

Date: December 4, 2019.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Nitsa Rosenzweig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4152, MSC 7760, Bethesda, MD 20892, (301) 404–7419, *rosenzweign@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Immunology AREA Review.

Date: December 4, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Liying Guo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016F, Bethesda, MD 20892, 301–435–0908, *lguo@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biological Chemistry and Macromolecular Biophysics.

Date: December 4, 2019.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Raymond Jacobson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5858, MSC 7849, Bethesda, MD 20892, 301–996–7702, *jacobsonrh@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–18–877: Early Stage Clinical Trials for the Spectrum of Alzheimer's Disease and Age-Related Cognitive Decline.

Date: December 4, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Unja Hayes, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–6830, *unja.hayes@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 7, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24776 Filed 11–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0565]

Lifejacket Approval Harmonization

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard is finalizing the policy harmonizing personal flotation device (PFD) standards between the United States and Canada by accepting a new standard for approval of PFDs. As a result, PFD manufacturers can meet a single North American standard instead of separate standards for the United States and Canada. The standard is outlined in a policy letter with a supporting deregulatory savings analysis. This policy letter is intended to promote the Coast Guard's maritime safety and stewardship missions. This policy does not affect existing PFD approvals and does not require any action on the part of boaters or mariners who have approved PFDs on board.

ADDRESSES: Documents mentioned in this notice, and all public comments, are available in our online docket at *http://www.regulations.gov,* and can be viewed by following that website's instructions.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Jacqueline Yurkovich, Coast Guard; telephone 202–372–1389, email *Jacqueline.M.Yurkovich@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background

On August 17, 2018, the United States Coast Guard (USCG) published a Notice of Availability and Request for Comments (83 FR 41095) announcing that it was harmonizing PFD standards between the United States and Canada by accepting a new standard for approval of PFDs. The Coast Guard outlined the new standard in a draft policy letter with a supporting deregulatory savings analysis and made those documents available for public comment. The Coast Guard received input from six commenters.

Discussion of Policy and Comments

The Notice of Availability (83 FR 41095) summarizes the background of the policy letter.

During the notice of availability comment period, the Coast Guard received input from six commenters, including mariners, the Life Jacket Association, the National Marine Manufacturers Association, and the Boat Owners Association of the United States. Below are summaries of, and our responses to, those comments.

Four commenters supported the efforts to harmonize the PFD standards with ISO 12402. One commenter also stated that they supported and appreciated the policy language stating that lifejackets already approved would remain in compliance with the new policy. Some commenters also suggested that the Coast Guard should broaden the categories of buoyancy to specifically allow Level 50 and youth inflatable PFDs in appropriate conditions. While the Coast Guard will not include additional categories in this policy letter, we will take the suggestions of the commenters under consideration in a future rulemaking.

One commenter stated that the Coast Guard should address potential confusion in the recreational boating community with regard to the new [policy] that ''Adult devices that cannot meet the requirements of Level 70 with inherent buoyancy alone must be marked 'Approval conditions state that this device must be worn to be counted as equipment required by vessels meeting Transport Canada or USCG regulations.' '' [1] As the Coast Guard accepts alternatives to the markings of inflatable PFDs, the commenter urged that consideration should also be given to adding markings that users need to test or inflate the devices regularly in order to be approved for use. The commenter stated that adding markings requiring inflatable PFD testing would be in keeping with current Coast Guard practices, such as those for PFD lights where alkaline batteries must be changed annually for devices to maintain their approval. The commenter concluded that, to this end, the USCG and Transport Canada should consider requiring inflatable PFD manufacturers to add inspection tags, similar to fire extinguisher inspection tags, to their PFDs where owners can record and be reminded of their periodic inspections and tests. Additionally, the commenter stated that the inflatable PFD age requirement of 16 should be lowered to age 13 to close the gap between the age requirement for wearing a PFD, located in 33 CFR 175.15 and the age range for an inflatable PFD because PFD options are more limited in the 13–16 age range. The Coast Guard acknowledges these concerns and suggestions and aims to address any potential confusion about the subject policy in this notice. With regard to adding new requirements that are not discussed in the new standard being accepted, such as for additional marking, testing, and inspection tags, these measures are outside of the scope of the policy letter that is the subject of this notice. These other measures may, however, be considered in future rulemaking. Similarly, the Coast Guard may consider the appropriateness of inflatable PFDs for wearers under 16 years of age in a future rulemaking.

The Coast Guard also received comments about the deregulatory savings analysis. Specifically, one commenter said that the cost savings analysis projects various hypothetical savings for the manufacturing sector and the U.S. Government without regard for the end users of the equipment (*e.g.,* boaters, their families, insurance companies, and community). The commenter also stated that deregulation proposed to benefit the manufacturers may overlook the intended purpose of life saving equipment and result in more costs to the boating public, the U.S. taxpayers, and the U.S. government. The commenter also suggested other modifications to law and policy that might increase benefits in terms of lives saved—such as improving the rate of wear, improving visibility of PFDs at nighttime, and considering user size and weight.

The Coast Guard acknowledges that this policy letter pertains to producers of lifejackets primarily. Some portion of the cost savings may be passed onto consumers by lowering the final purchase price of lifejackets for consumers; however, the Coast Guard has no data to indicate what share of the cost savings would be passed onto consumers. Additionally, the Coast Guard has no evidence that this policy would harm the boating public. The Coast Guard determined that the PFDs permitted by this policy letter provide equivalent performance to a PFD that meets the requirements of 46 CFR 160.064, 160.076, or 160.077–15. Further, were any share of the cost savings estimated here to be passed onto consumers, the safety of the boating public would be increased as lifejackets would be cheaper. However, the stated goal of the policy letter is harmonization via a single standard for manufacturers to meet. The Coast Guard will consider this commenter's other suggestions for possible future action.

The commenter also said that the international agreement should factor in tariffs, exchange rates, trade agreements, and currency valuations. It is not clear how such secondary impacts would affect harmonizing PFD standards between the United States and Canada and the commenter did not describe how such secondary impacts were relevant to this particular harmonization. Consequently, the Coast Guard does not believe these secondary impacts are relevant to this issue.

The same commenter said that the lifejackets used in the United States and Canada are used in various water conditions and weather conditions impacting their effectiveness, and that the length of time that a boater has been in the water and the body of water the boater is rescued from all have different characteristics impacting the effectiveness of lifejackets.

The commenter argued the maximum cost savings could be realized by ensuring that each and every boater who is on the water is properly equipped with the correct lifejackets because historically most drownings involve boaters without lifejackets. The Coast Guard considers such additional requirements to be outside the scope of this policy letter.

Cost Savings Analysis

Since the affected population and projected cost-savings estimates have

[1] Document number USCG–2018–0565–0008 at *http://www.Regulations.gov* under docket number USCG–2018–0565.

remained the same from when we published the deregulatory savings analysis in August 2018, we have retained the projected cost-saving estimates for this notice, which we present below. As stated in the aforementioned economic analysis, which is available in the public docket, we estimate the annual net cost savings to the U.S. industry to be $660,965 in 2016 dollars using a 7-percent discount rate over a 10-year period of analysis. We estimate the total discounted net cost savings to U.S. industry over a 10-year period of analysis to be between $4.6 million and $5.7 million at 7- and 3-percent discount rates, respectively.

We estimate the annual net cost savings to the U.S. government to be $8,571 per year over a 10-year period of analysis at a 7-percent discount rate. We estimate the total discounted net cost savings to the U.S. government to be between $60,000 and $73,000 at 7- and 3-percent discount rates, respectively.

We also estimate an annual net cost savings to foreign manufacturers of $406,758 in 2016 dollars using a 7-percent discount rate over a 10-year period of analysis. We estimate the total discounted net cost savings to foreign industry over a 10-year period of analysis to be between $2.9 million and $3.5 million at 7- and 3-percent discount rates, respectively.

We estimate the costs to industry from this policy letter as a one-time switching cost between $40,000 and $41,000 at 7- and 3-percent discount rates, respectively.

Under a perpetual period of analysis, we estimate the total annualized cost savings of our policy letter to the U.S. economy to be $546,065 in 2016 dollars, using a 7-percent discount rate, and discounted back to 2016.

This notice is issued under authority of 5 U.S.C. 552(a).

Dated: November 7, 2019.

J.G. Lantz,

Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2019–24836 Filed 11–14–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–NEW]

Agency Information Collection Activities: 321 E-Commerce Data Pilot

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; New collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted no later than December 16, 2019 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (84 FR 48363) on September 13, 2019, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: 321 E-Commerce Data Pilot.
OMB Number: 1651–NEW.
Form number: N/A.
Current Actions: This submission is being made to obtain an OMB control number for this Information Collection Request and to expand the respondent group of the recent 321 Data Pilot test notice on July 23, 2019 (84 FR 35405) which was limited to nine respondents.
Type of Review: New.
Affected Public: Businesses.
Abstract: CBP faces significant challenges in targeting Section 321 shipments, while still maintaining the clearance speeds the private sector has come to expect. This is because CBP does not receive adequate advance information in order to effectively and efficiently assess the security risk of the approximately 1.8 million Section 321 shipments that arrive each day. This pilot is conducted pursuant to 19 CFR 101.9(a), which authorizes the Commissioner to impose requirements different from those specified in the CBP regulations for the purposes of conducting a test program or procedure designed to evaluate the effectiveness of new technology or operational procedures regarding the processing of passengers, vessels, or merchandise.

In the e-commerce environment, traditionally regulated parties, such as carriers, are unlikely to possess all of the information relating to a shipment's supply chain. While CBP receives some advance electronic data for Section 321 shipments from air, rail, and truck carriers (and certain other parties in limited circumstances) as mandated by current regulations, the transmitted data often does not adequately identify the

entity causing the shipment to cross the border, the final recipient, or the contents of the package. Consequently, CBP may not receive any advance information on the entity actually causing the shipment to travel to the United States, such as the seller or manufacturer. Some carriers may not have this information because sellers on e-commerce platforms often contract with other entities to act as the seller. Similarly, for the consignee's name and address, a carrier might transmit information for the domestic deconsolidator, which will not allow CBP to identify in advance of arrival, the final recipient of the merchandise in the United States. With the growth of e-commerce, shipments are increasingly subject to these complex transactions, where information about the shipment is limited. As a result, CBP is less able to effectively target or identify high-risk shipments in the e-commerce environment and CBP Officers must use additional time and resources to inspect Section 321 shipments upon arrival.

CBP anticipates that Section 321 shipments will continue to grow quickly. Accordingly, CBP is initiating this voluntary Section 321 Data Pilot to test the feasibility of obtaining advance information from regulated and non-regulated entities, such as online marketplaces, as well as requiring additional advance data elements. This test will enable CBP to assess the ability of online marketplaces to transmit information to CBP that enables CBP to better use resources used in inspecting and processing these shipments and better understand the operation of online marketplaces. Additionally, CBP is testing whether the transmission of additional advance data, beyond the data elements currently required for shipments arriving by air, truck, or rail, will enable CBP to more accurately and efficiently target Section 321 shipments. Pursuant to this test, participants will provide information that identifies the entity causing the shipment to cross the border, the ultimate recipient, and the product in the shipment with greater specificity, in advance. CBP will test the feasibility of using the additional data elements, transmitted by multiple entities for a single shipment, to segment risk. In sum, the pilot will enable CBP to determine if requiring additional data and involving non-regulated entities will enable CBP to address the threats and complexities resulting from the vast increase in Section 321 shipments, while facilitating cross-border e-commerce.

Participants in the Section 321 Data Pilot must transmit certain information for any Section 321 shipments destined for the United States for which the participant has information. The required data elements differ slightly depending on what entity is transmitting the data. In general, the required data relates to the entity initiating the shipment (*e.g.,* the entity causing the shipment to cross the border, such as the seller, manufacturer, or shipper), the product in the package, the listed marketplace price, and the final recipient (*e.g.,* the final entity to possess the shipment in the United States). The data elements are as follow.

1. All participants. All participants, regardless of filer type, must electronically transmit the following elements:

- Originator Code of the Participant (assigned by CBP)
- Participant Filer Type (*e.g.,* carrier or online marketplace)
- One or more of the following:
  - Shipment Tracking Number
  - House Bill Number
  - Master Bill Number
- Mode of Transportation (*e.g.,* air, truck, rail, or ocean)

2. Participating carriers. In addition to the data elements listed above in paragraph 1, participating carriers must also electronically transmit the following data elements:

- Shipment Initiator Name and Address (*e.g.,* the entity that causes the movement of a shipment, which may be a seller, shipper, or manufacturer, but not a foreign consolidator)
- Final Deliver to Party Name and Address (*e.g.,* the final entity to receive the shipment once it arrives in the United States, which may be a final purchaser or a warehouse, but not a domestic deconsolidator)
- Enhanced Product Description (*e.g.,* a description of a product shipped to the United States more detailed than the description on the manifest, which should, if applicable, reflect the advertised retail description of the product as listed on an online marketplace)
- Shipment Security Scan (air carriers only) (*e.g.,* verification that a foreign security scan for the shipment has been completed such as an x-ray image or other security screening report)
- Known Carrier Customer Flag (*e.g.,* an indicator that identifies a shipper as a repeat customer that has consistently paid all required fees and does not have any known trade violations)

3. Participating online marketplaces. In addition to the data elements listed above in paragraph 1, participating online marketplaces must electronically submit the following data elements:

- Seller Name and Address (*e.g.,* an international or domestic company that sells products on marketplaces and other websites), and, if applicable, Shipment Initiator Name and Address (as defined in Section II.A.2)
- Final Deliver to Party Name and Address (as defined in Section II.A.2)
- Known Marketplace Seller Flag (*e.g.,* an indicator provided by a marketplace that identifies a seller as an entity vetted by the marketplace and has no known trade violations)
- Marketplace Seller Account Number/Seller ID (*e.g.,* the unique identifier a marketplace assigns to sellers)
- Buyer Name and Address, if applicable (*e.g.,* the purchaser of a good from an online marketplace. This entity is not always the same as the final deliver to party.)
- Product Picture (*e.g.,* picture of the product presented on an online marketplace), Link to Product Listing (*e.g.,* an active and direct link to the listing of a specific product on an online marketplace), or Enhanced Product Description (as defined in Section II.A.2)
- Listed Price on Marketplace (*e.g.,* the retail price of a product that a seller lists while advertising on an online marketplace. For auction marketplaces, this price is the price of final sale.)

Different entities may transmit different data elements for the same shipment. In addition to the above required data elements, participants may voluntarily provide the following optional data elements:

- HTS Number;
- Retail Price in Export Country;
- Shipper Name;
- Shipper Address;
- Shipper Phone Number;
- Shipper Email Address;
- Shipment Initiator Phone Number;
- Consignee Name;
- Consignee Address;
- Consignee Phone Number;
- Consignee Email Address;
- Marketplace Name;
- Buyer Account Number;
- Buyer Address;
- Seller Phone Number;
- Buyer Phone Number;
- Marketplace website;
- Buyer Name;
- Buyer Confirmation Number;
- Buyer Email Address;
- Carrier Name;
- Known Carrier Customer;
- Merchandise/Product Weight; and,
- Merchandise/Product Quantity.

• Listed Price on Marketplace.

Estimated Number of Respondents: 20.

Estimated Number of Annual Responses per Respondent: 70,000.

Estimated Number of Total Annual Responses: 1,400,000.

Estimated Time per Response: 5 seconds.

Estimated Total Annual Burden Hours: 1,944.

Dated: November 12, 2019.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2019–24800 Filed 11–14–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4467–DR; Docket ID FEMA–2019–0001]

South Dakota; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of South Dakota (FEMA–4467–DR), dated October 7, 2019, and related determinations.

DATES: The declaration was issued October 7, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 7, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of South Dakota resulting from severe storms, tornadoes, and flooding during the period of June 30 to July 21, 2019, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of South Dakota.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James R. Stephenson, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of South Dakota have been designated as adversely affected by this major disaster:

Butte, Gregory, Kingsbury, Lawrence, Meade, and Tripp Counties and the Cheyenne River Tribe of the Cheyenne River Sioux Reservation and the Lower Brule Tribe of the Lower Brule Reservation for Public Assistance.

All areas within the State of South Dakota are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–24839 Filed 11–14–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3425–EM; Docket ID FEMA–2019–0001]

Commonwealth of the Northern Mariana Islands; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the Commonwealth of the Northern Mariana Islands (FEMA–3425–EM), dated October 20, 2019, and related determinations.

DATES: The declaration was issued October 20, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 20, 2019, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the Commonwealth of the Northern Mariana Islands resulting from Typhoon Bualoi beginning on October 20, 2019, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the Commonwealth of the Northern Mariana Islands.

You are authorized to provide appropriate assistance for required emergency measures, authorized under title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Teresa Serata, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the Commonwealth of the Northern Mariana Islands have been designated as adversely affected by this declared emergency:

The municipalities of Rota, Saipan, Tinian, and the Northern Islands for emergency protective measures (Category B), limited to direct Federal assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–24846 Filed 11–14–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4455–DR; Docket ID FEMA–2019–0001]

West Virginia; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for Commonwealth of West Virginia (FEMA–4455–DR), dated August 2, 2019, and related determinations.

DATES: This change occurred on October 24, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael Senycz, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Jason Burroughs as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–24843 Filed 11–14–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4461–DR; Docket ID FEMA–2019–0001]

Illinois; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Illinois (FEMA–4461–DR), dated September 19, 2019, and related determinations.

DATES: This amendment was issued October 24, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Illinois is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of September 19, 2019.

Lee County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–24842 Filed 11–14–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4464–DR; Docket ID FEMA–2019–0001]

South Carolina; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of South Carolina (FEMA–4464–DR), dated September 30, 2019, and related determinations.

DATES: This amendment was issued November 5, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of South Carolina is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the

President in his declaration of September 30, 2019.

Allendale County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–24841 Filed 11–14–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4468–DR; Docket ID FEMA–2019–0001]

Florida; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Florida (FEMA–4468–DR), dated October 21, 2019, and related determinations.

DATES: The declaration was issued October 21, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 21, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Florida resulting from Hurricane Dorian during the period of August 28 to September 9, 2019, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Florida.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Thomas J. McCool, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Florida have been designated as adversely affected by this major disaster:

Brevard, Duval, Flagler, Indian River, Martin, Nassau, Osceola, Palm Beach, Putnam, Seminole, St. Johns, and St. Lucie Counties for Public Assistance.

All areas within the State of Florida are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–24838 Filed 11–14–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4466–DR; Docket ID FEMA–2019–0001]

Texas; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4466–DR), dated October 4, 2019, and related determinations.

DATES: This amendment was issued October 24, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 4, 2019.

San Jacinto County for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–24840 Filed 11–14–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2019–0015]

Notice of the President's National Infrastructure Advisory Council Meeting

AGENCY: Cybersecurity and Infrastructure Security Agency, DHS.

ACTION: Announcement of meeting; request for comments.

SUMMARY: The Cybersecurity and Infrastructure Security Agency (CISA) announces a public meeting of the President's National Infrastructure Advisory Council (NIAC). To facilitate public participation, CISA invites public comments on the agenda items and any associated briefing materials to be considered by the council at the meeting.

DATES:

Meeting Registration: Individual registration to attend the meeting in person is required and must be received no later than 5:00 p.m. EST on December 12, 2019.

Speaker Registration: Individuals may register to speak during the meeting's public comment period must be received no later than 5:00 p.m. EST on December 4, 2019.

Written Comments: Written comments must be received no later than 12:00 p.m. EST on December 11, 2019.

NIAC Meeting: The meeting will be held on Thursday, December 12, 2019 from 9:00 a.m.–1:00 p.m. EST.

ADDRESSES: The NIAC meeting will be held at the Eisenhower Executive Office Building, 1650 Pennsylvania Ave. NW, Washington, DC 20502.

Comments: Written comments may be submitted on the issues to be considered by the NIAC as described in the **SUPPLEMENTARY INFORMATION** section below and any briefing materials for the meeting. Any briefing materials that will be presented at the meeting will be made publicly available on Friday, December 6, 2019 at the following website: *https://www.dhs.gov/national-infrastructure-advisory-council.*

Comments identified by docket number ''*CISA–2019–0015*'' may be submitted by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting written comments.
- *Email: NIAC@hq.dhs.gov.* Include docket number *CISA–2019–0015* in the subject line of the message.
- *Fax:* 703–235–9707, ATTN: Ginger K. Norris.
- *Mail:* Ginger K. Norris, Designated Federal Officer, National Infrastructure Advisory Council, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security, 245 Murray Lane, Mail Stop 0612, Arlington, VA 20598–0612.

Instructions: All submissions received must include the agency name and docket number for this notice. All written comments received will be posted without alteration at *www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on participating in the upcoming NIAC meeting, see the ''PUBLIC PARTICIPATION'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket and comments received by the NIAC, go to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ginger K. Norris, 202–441–5885, *ginger.norris@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION: The NIAC is established under Section 10 of E.O. 13231 issued on October 16, 2001. Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix (Pub. L. 92–463). The NIAC shall provide the President, through the Secretary of Homeland Security, with advice on the security and resilience of the Nation's critical infrastructure sectors.

The NIAC will meet in an open meeting on December 12, 2019, to discuss the following agenda items with DHS leadership.

Agenda

I. Call to Order
II. Opening Remarks
III. Insurance Panel Discussion
IV. Discuss and Deliberate Current Task
V. Public Comment
VI. Closing Remarks
VII. Adjournment

Public Participation

Meeting Registration Information

Due to additional access requirements and limited seating, requests to attend in person will be accepted and processed in the order in which they are received. Individuals may register to attend the NIAC meeting by sending an email to *NIAC@hq.dhs.gov.*

Public Comment

While this meeting is open to the public, participation in FACA deliberations are limited to council members. A public comment period will be held during the meeting from approximately 12:45 p.m.–1:00 p.m. EST. Speakers who wish to comment must register in advance and can do so by emailing *NIAC@hq.dhs.gov* no later than Wednesday, December 4, 2019, at 5:00 p.m. EST. Speakers are requested to limit their comments to three minutes. Please note that the public comment period may end before the time indicated, following the last call for comments.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact *NIAC@hq.dhs.gov* as soon as possible.

Dated: November 6, 2019.

Ginger K. Norris,

Designated Federal Official, National Infrastructure Advisory Council, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2019–24744 Filed 11–14–19; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY925000.L13400000.PQ0000 20X]

Notice of Intent To Prepare Resource Management Plan Amendments for 9 BLM-Wyoming Resource Management Plans and an Associated Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, and the Federal Land Policy and Management Act (FLPMA) of 1976, as amended, the Bureau of Land Management (BLM) intends to prepare an Environmental Impact Statement (EIS) to analyze potential Resource Management Plan (RMP) amendments for BLM Wyoming's Cody, Worland, Buffalo, Casper, Lander, Pinedale, Kemmerer, Rawlins and Rock Springs field offices. The proposed amendments would designate pipeline corridors as part of the Wyoming Pipeline Corridor Initiative (WPCI) proposed by the State of Wyoming. By this notice, the BLM is announcing the beginning of the scoping process to solicit public comments and identify issues.

DATES: Comments on the RMP amendments and associated EIS may be submitted in writing until December 16, 2019. The date(s) and location(s) of any

scoping meetings will be announced at least 15 days in advance through local media, newspapers and the BLM website at *https://go.usa.gov/xpCMr.* To ensure the BLM can adequately consider and incorporate all comments, please submit written comments prior to the close of the 30-day scoping period or 15 days after the last public meeting, whichever is later. The BLM will provide additional opportunities for public participation upon publication of the Draft EIS.

ADDRESSES: You may submit comments on issues and planning criteria related to the EIS during public scoping meetings or on the WPCI ePlanning website at *https://go.usa.gov/xpCMr.*

Documents pertinent to this proposal may be examined in person at the BLM Wyoming State Office, 5353 Yellowstone Road, Cheyenne, WY 82009.

FOR FURTHER INFORMATION CONTACT: Heather Schultz, Project Manager, telephone: 307–775–6084; address: 5353 Yellowstone Road, Cheyenne, Wyoming; email: *hschultz@blm.gov.* Contact Ms. Schultz to be added to the WPCI mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The State of Wyoming is proposing a pipeline corridor network for carbon capture, utilization, and storage (CCUS) and enhanced oil recovery (EOR) to be designated on BLM-managed lands in Wyoming through the land use planning process. The State of Wyoming proposes that 2,000 miles and 25 segments of pipeline corridors be designated on BLM-managed lands and in those lands' associated RMPs. The proposed WPCI corridors are divided into segments based on proposed width and the regions they will service.

The BLM plans to analyze the State's proposal by preparing an EIS. Based on the findings of the EIS process, the BLM may amend the nine RMPs containing lands proposed for pipeline corridors to designate those corridors. If the BLM were to receive a right-of-way application for CCUS and EOR pipelines or related facilities in the future, project-specific NEPA would be completed separately at that time. The purpose of this public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the planning process. BLM and State of Wyoming personnel have identified preliminary issues to address within the planning area, including Greater Sage-Grouse; big game habitat (including migration corridors); potential conflicts with coal mining and other resource uses; air quality; transportation; vegetation and reclamation success; anticipated oil and gas development in the planning area; and opportunities to apply best management practices and design features.

The BLM also seeks input on planning criteria, which include compliance with laws and regulations and integration into affected plans. The BLM has identified the following preliminary planning criteria:

- The planning and environmental review processes will comply with FLPMA, the Endangered Species Act, the Clean Water Act, and all other applicable laws, regulations, and policies.
- Valid existing rights will continue to be recognized.
- The BLM will continue to manage other resources in the planning areas under pre-existing terms, conditions, and decisions in the applicable RMPs.
- The BLM will coordinate with Federal, State, and local agencies and tribal governments in the development of the EIS.
- Any amendments to BLM RMPs will be consistent with the existing plans and policies of state and local governments, to the extent practicable.

Please follow the procedures identified above to submit comments on issues and planning criteria. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. The BLM will evaluate identified issues to be addressed in the plan, and will place them into one of three categories:

1. Issues to be resolved in the plan;
2. Issues to be resolved through policy or administrative action; or
3. Issues beyond the scope of this plan.

The BLM will provide an explanation in the Draft RMP/Draft EIS as to why an issue was placed in category 2 or 3. The public is also encouraged to help identify any management questions and concerns that should be addressed in the plan. The BLM will work collaboratively with interested parties to identify the management decisions that are best suited to local, regional, and national needs and concerns.

The BLM will utilize and coordinate the NEPA scoping process to help fulfill the public involvement process under the National Historic Preservation Act (54 U.S.C. 306108) as provided in 36 CFR 800.2(d)(3). The information about historic and cultural resources within the area potentially affected by the proposed action will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will use an interdisciplinary approach to develop the plan in order to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in the planning process: Rangeland management, minerals and geology, forestry, outdoor recreation, archaeology, paleontology, wildlife and fisheries, lands and realty, hydrology, soils, sociology, and economics.

Authority: 40 CFR 1501.7, 43 CFR 1610.2.

Duane Spencer,

Acting State Director.

[FR Doc. 2019–24752 Filed 11–14–19; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF JUSTICE

Agency Information Collection Activities; Proposed Collection; Comments Requested; Immigration Practitioner Complaint Form

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 30-Day notice.

The Department of Justice (DOJ), Executive Office for Immigration Review, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional days until December 16, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lauren Alder Reid, Assistant Director,

Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500, Falls Church, VA 22041, telephone: (703) 305–0289. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Executive Office for Immigration Review, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of information collection:* Extension without change of a currently approved collection.

2. *The title of the form/collection:* Immigration Practitioner Complaint Form.

3. *The agency form number, if any, and the applicable component of the department sponsoring the collection:* Form EOIR–44. The applicable component within the Department of Justice is the Office of General Counsel, Executive Office for Immigration Review.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals who wish to file a complaint against an immigration practitioner authorized to appear before the Board of Immigration Appeals and the immigration courts. Abstract: The information on this form will be used to determine whether the Office of the General Counsel of the Executive Office for Immigration Review should conduct a preliminary disciplinary inquiry, request additional information from the complainant, refer the matter to a state bar disciplinary authority or other law enforcement agency, or take no further action.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 200 respondents will complete the form annually, with an average of 2 hours per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 400 hours. It is estimated that respondents will take 2 hours to complete the form. The burden hours for collecting respondent data sum to 400 hours (200 respondents × 2 hours = 400 hours).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: November 12, 2019.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–24794 Filed 11–14–19; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE

[OMB Number 1125–0012]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Request for New Recognition, Renewal of Recognition, Extension of Recognition of a Non-Profit Religious, Charitable, Social Service, or Similar Organization (Form EOIR–31)

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review (EOIR), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on September 5, 2019, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until December 16, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500, Falls Church, VA 22041, telephone: (703) 305–0289. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of information collection:* Extension with changes of a currently approved collection.

2. *The title of the form/collection:* Request for New Recognition, Renewal of Recognition, Extension of Recognition of a Non-profit Religious, Charitable, Social Service, or Similar Organization.

3. *The agency form number:* Form EOIR–31 (OMB 1125–0012).

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Non-profit organizations seeking new recognition, renewal of recognition, or extension of recognition to be recognized as legal service providers by the Office of Legal Access Programs of the Executive Office for Immigration Review (EOIR). Abstract: This information collection will allow an organization for new recognition, renewal of recognition, or extension of recognition to appear before EOIR and/or the Department of Homeland Security. This information collection is necessary to determine whether an organization meets the eligibility requirements for recognition.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 129 respondents will complete the form for new recognition annually with an average of 2 hours per response. It is estimated that 131 respondents will complete the form for renewal of recognition annually with an average of 7 hours per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1175 (258 for new + 917 for renewals) total annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: November 12, 2019.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–24795 Filed 11–14–19; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE

[OMB Number 1125–0013]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Request by Organization for Accreditation or Renewal of Accreditation of Non-Attorney Representative (Form EOIR–31A)

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review (EOIR), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on September 5, 2019, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until December 16, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500, Falls Church, VA 22041, telephone: (703) 305–0289. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of information collection:* Extension with changes of a currently approved collection.

2. *The title of the form/collection:* Request by Organization for Accreditation or Renewal Accreditation of Non-Attorney Representative.

3. *The agency form number:* Form EOIR–31A (OMB 1125–0013).

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Non-profit organizations seeking accreditation or renewal of accreditation of its representatives by the Office of Legal Access Programs of the Executive Office for Immigration Review (EOIR). Abstract: This information collection will allow an organization to seek accreditation or renewal of accreditation of a non-attorney representatives to appear before EOIR and/or the Department of Homeland Security. This information collection is necessary to determine whether a representatives meet the eligibility requirements for accreditation.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 818 respondents will complete the form annually with an average of 2 hours per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,636 total annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: November 12, 2019.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–24796 Filed 11–14–19; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Program Reporting and Performance Standards System for Indian and Native American Programs Under Title I, Section 166 of the Workforce Innovation and Opportunity Act (WIOA)

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL's) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Program Reporting and Performance Standards System for Indian and Native American Programs Under Title I, Section 166 of the Workforce Innovation and Opportunity Act (WIOA).'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by January 14, 2020.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Athena R. Brown by telephone at (214) 906–3902 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *brown.athena@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Division of Indian and Native American Programs, 200 Constitution Ave. NW, Rm. # S–4206, Washington, DC 20210; by email: *DINAP@dol.gov;* or by Fax (202) 693–3817.

FOR FURTHER INFORMATION CONTACT: Duane Hall by telephone at (972) 850–4637 (this is not a toll-free number) or by email at *hall.duane@dol.gov.*

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

ETA requires the collection and reporting of data on eligible persons served under the WIOA, Section 166, Comprehensive Services Program (CSP) and Supplemental Youth Services (SYS) Program to assess the performance and delivery of services. Each Indian and Native American (INA) grantee receiving WIOA, Section 166 funds (non-Pub. L. 102–477 grantees) shall submit a CSP report (ETA Form 9084) on a quarterly basis. Grantees receiving WIOA Section 166 (SYS) funds (non-Pub. L. 102–477 grantees) shall submit a SYS program report (ETA Form 9085) semi-annually. This request is to extend the existing ETA form 9084 and 9085 report submitted each quarter/semi-annually, by INA grantees. The current ETA forms 9084 and 9085 expire on January 31, 2020. 29 U.S.C. Chapter 30, Subchapter V, § 2935(2), authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB control number 1205–0422.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.

Type of Review: Extension without changes.

Title of Collection: Program Reporting and Performance Standards System for Indian and Native American Programs Under Title I, Section 166 of the Workforce Innovation and Opportunity Act (WIOA).

Form: ETA–9084 and ETA–9085.

OMB Control Number: 1205–0422.

Affected Public: State, local and Tribal Governments.

Estimated Number of Respondents: 111 respondents to the CSP and 73 respondents to the SYS.

Frequency: Quarterly for the CSP (Form ETA–9084) and semi-annually for the SYS (Form ETA–9085).

Total Estimated Annual Responses: 440 respondents to the CSP and 146 respondents to the SYS.

Estimated Average Time per Response: 2 hours for the CSP and 2 hours for the SYS.

Estimated Total Annual Burden Hours: 1,180 hours.

Total Estimated Annual Other Cost Burden: $0.

John Pallasch,

Assistant Secretary for Employment and Training.

[FR Doc. 2019–24831 Filed 11–14–19; 8:45 am]

BILLING CODE 4510–FR–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act: Notice of Agency Meeting

TIME AND DATE: 10:00 a.m., Wednesday, November 20, 2019.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street (All visitors

must use Diagonal Road Entrance), Alexandria, VA 22314–3428.

STATUS: Open.

MATTERS TO BE CONSIDERED: 1. Board Briefing, NCUA's 2020–2021 Budget.

FOR FURTHER INFORMATION CONTACT: Gerard Poliquin, Secretary of the Board, Telephone: 703–518–6304.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2019–24928 Filed 11–13–19; 4:15 pm]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request; NCUA Profile

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: The National Credit Union Administration (NCUA), as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the following revision, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before January 14, 2020 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dawn Wolfgang, National Credit Union Administration, 1775 Duke Street, Suite 6032, Alexandria, Virginia 22314; Fax No. 703–519–8579; or Email at *PRAComments@NCUA.gov.*

FOR FURTHER INFORMATION CONTACT: Address requests for additional information to Dawn Wolfgang at the address above or telephone 703–548–2279.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0004. At the time of this notice, NCUA is requesting a separate OMB control number for the Profile. The Call Report will retain OMB control number 3133–0004.

Title: NCUA Profile.

Form: NCUA Form 4501A.

Type of Review: Revision.

Abstract: Sections 106 and 202 of the Federal Credit Union Act require federally insured credit unions (FICU) to make financial reports to the NCUA. Section 741.6 prescribes the method in which federally insured credit unions must submit this information to NCUA. NCUA Form 4501A, Credit Union Profile, is used to obtain non-financial data relevant to regulation and supervision such as the names of senior management and volunteer officials, and are reported through NCUA's online portal, CUOnline.

The financial and statistical information is essential to NCUA in carrying out its responsibility for supervising federal credit unions. The information also enables NCUA to monitor all federally insured credit unions with National Credit Union Share Insurance Fund (NCUSIF) insured share accounts.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated No. of Respondents: 5,308.

Estimated No. of Responses per Respondent: 4.

Estimated Total Annual Responses: 21,232.

Estimated Burden Hours per Response: 2.

Estimated Total Annual Burden Hours: 42,464.

Reason for Change: Revisions include the addition of two questions addressing London Interbank Offered Rate (LIBOR) exposure. These questions are needed to identify FICU that have LIBOR instruments or use LIBOR as a reference rate. Examiners will use this information to assess credit unions' exposure, governance, risk management and readiness related to the discontinuation of the LIBOR index after 2021.

This revision will not alter the estimated burden hours necessary to complete the profile. The information needed to provide a ''yes'' or ''no'' response is readily available and NCUA feels that the two hours currently allotted to complete the Form 4501A is sufficient.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper execution of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on November 8, 2019.

Dated: November 8, 2019.

Dawn D. Wolfgang,

NCUA PRA Clearance Officer.

[FR Doc. 2019–24760 Filed 11–14–19; 8:45 am]

BILLING CODE 7535–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of November 18, 25, December 2, 9, 16, 23, 2019.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of November 18, 2019

There are no meetings scheduled for the week of November 18, 2019.

Week of November 25, 2019—Tentative

There are no meetings scheduled for the week of November 25, 2019.

Week of December 2, 2019—Tentative

Wednesday, December 4, 2019

9:00 a.m. Strategic Programmatic Overview of the Fuel Facilities and the Spent Fuel Storage and Transportation Business Lines (Public Meeting); (Contact: Damaris Marcano: 301–415–7328).

This meeting will be webcast live at the Web address—*https://www.nrc.gov/.*

Friday, December 6, 2019

10:00 a.m. Meeting with Advisory Committee on Reactor Safeguards (Public Meeting); (Contact: Larry Burkhart: 301–287–3775).

This meeting will be webcast live at the Web address—*https://www.nrc.gov/.*

Week of December 9, 2019—Tentative

There are no meetings scheduled for the week of December 9, 2019.

Week of December 16, 2019—Tentative

Tuesday, December 17, 2019

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public Meeting); (Contact: Larniece McKoy Moore: 301–415–1942).

This meeting will be webcast live at the Web address—*https://www.nrc.gov/.*

Week of December 23, 2019—Tentative

There are no meetings scheduled for the week of December 23, 2019.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or by email at *Tyesha.Bush@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated at Rockville, Maryland, this 13th day of November 2019.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2019–24949 Filed 11–13–19; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0226]

Agency Action Regarding the Exploratory Process for the Development of an Advanced Nuclear Reactor Generic Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Gather information that would be used to determine whether to prepare a Generic Environmental impact statement for the construction and operation of advanced nuclear reactors.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is conducting an exploratory process to gather information on potential environmental impacts resulting from the construction and operation of advanced nuclear reactors. The NRC is planning to conduct two public meetings and a workshop to explore the interaction of various advanced nuclear reactor designs with the environment. NRC intends to gather information that will inform its decision on whether to proceed with the development of a generic environmental impact statement for the construction and operation of advanced nuclear reactors (ANR GEIS). The intent of an ANR GEIS is to improve the efficiency of the environmental review process.

DATES: The NRC intends to hold two public meeting in November of 2019 to solicitate public input regarding the development of an ANR GEIS. The NRC anticipates that the public workshop would occur during the month of December 2019.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0226. Address questions about NRC dockets IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: AdvancedReactors-GEIS.resource@nrc.gov.*
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jack Cushing, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1424, and email: *Jack.Cushing@nrc.gov.* Mallecia Sutton, Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0673, and email: *Mallecia.Sutton@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0226 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0226.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2019–0226 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

The NRC is soliciting input from stakeholders regarding the development of an ANR GEIS for the construction and operation of advanced nuclear reactors. The NRC will hold two public meetings during the month of November 2019 and a workshop in December 2019 to discuss stakeholder input. The NRC expects to gather input from stakeholders until December 31, 2019.

If developed, an ANR GEIS would streamline the environmental review process for advanced nuclear reactor environmental reviews. The ANR GEIS

would also determine which environmental impacts would result in essentially the same (generic) impact for various types of advanced nuclear power plants and which ones could result in different levels of environmental impacts requiring a plant-specific analysis. Environmental reviews for advanced nuclear reactor licenses would incorporate the ANR GEIS by reference and provide site-specific information in a supplemental Environmental Impact Statement, thereby streamlining the environmental review process.

The input received in the public meetings will inform the NRC on whether to prepare an ANR GEIS. If, after gathering stakeholder input, the NRC has sufficient information to begin development of a GEIS, the staff will begin the scoping process and develop a schedule for completion of an ANR GEIS at that time.

III. Request for Information

This notice informs the public of the NRC's intention to gather input from stakeholders to assess whether to proceed with the development of an ANR GEIS.

The NRC will need to:

a. Seek and obtain input from stakeholders on whether an ANR GEIS would improve the efficiency of the environmental review process, where the advanced nuclear reactors would be located, the types of technologies that would be involved, and which environmental impacts should be addressed in the ANR GEIS;

b. Assess whether an ANR GEIS could avoid duplication of effort and focus the review on important environmental issues; and

c. Investigate how an ANR GEIS can align with the goals and best practices of Federal government efforts to streamline the National Environmental Policy Act processes.

Below are specific questions that the NRC is seeking stakeholder feedback on:

a. Should the scope of the ANR GEIS include reactors regardless of technology or be limited to specific reactor technologies?

b. What reactor sizes (footprint) and power levels should the NRC include in the scope the ANR GEIS?

c. One possible option NRC is considering is limiting the ANR GEIS to certain regions with common environmental conditions. Should the NRC consider the geographical site of a reactor when developing the scope of the ANR GEIS? Should the NRC consider a set of bounding plant parameters when developing the scope of the ANR GEIS? If so, what parameters should be considered?

IV. Public Meetings and Workshop

The NRC will hold two Category 2 public meetings to solicitate information regarding development of an ANR GEIS. The two meetings will be held in November 2019 and the workshop will be held in December 2019. The meeting dates and locations will be posted on the NRC's public website at *https://www.nrc.gov/pmns/mtg.* The public is invited to discuss regulatory issues with the agency at designated points that will be identified on the agenda. The NRC's Policy Statement, ''Enhancing Public Participation on NRC Meetings,'' effective May 28, 2002 (67 FR 36920), applies to this meeting. The policy statement may be found electronically under the NRC's public website (*https://www.nrc.gov/reading-rm/doc-collections/commission/policy/67fr36920.html*), and contains information regarding visitors and security.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in this meeting or need the meeting notice or the transcript or other information from the meeting in another format (*e.g.,* Braille, large print), please notify the NRC's meeting contact. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

V. Procedural Requirements

Paperwork Reduction Act Statement

This **Federal Register** Notice does not contain new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing information collection requirements were approved by the Office of Management and Budget (OMB), approval number 3150–0021.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

Dated at Rockville, Maryland, this 12th day of November 2019.

For the Nuclear Regulatory Commission.

John R. Tappert,

Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2019–24792 Filed 11–14–19; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Wednesday, November 20, 2019.

PLACE: The meeting will be held at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matters of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: November 13, 2019.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2019–24955 Filed 11–13–19; 4:15 pm]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA 2019–0048]

National Disability Forum

AGENCY: Social Security Administration (SSA).

ACTION: Announcement of a National Disability Forum.

SUMMARY: We are announcing the fourteenth National Disability Forum. The purpose of this public forum is to obtain feedback from experts in their field on what impairments have a likelihood to improve. This forum will be moderated, and include up to five panelists presenting information on the topic. Additionally, there will be a combined question and answer session during which the panelists will address questions from those on site and received by email during the forum.

DATES: Tuesday December 3, 2019 from 1:00 p.m. to 3:00 p.m.

ADDRESSES: *Meeting Location:* Partnership for Public Service, 1100 New York Ave NW, Suite 200 East, Washington, DC 20005.

Accommodations: Sign language interpreters, microphones, and materials in Braille, large print, and electronic formats will be available. The facility is wheelchair accessible. Anyone needing other accommodations should include a specific request when registering in advance.at: *https://www.ssa.gov/ndf/*.

FOR FURTHER INFORMATION CONTACT: James Edrington, NDF Team Lead, Office of Medical Assistance, Social Security Administration, 4539 Annex, 6401 Security Boulevard, Baltimore, MD 21235–6401, Telephone: (410) 966–2153, or send

SUPPLEMENTARY INFORMATION: The National Disability Forum is an open forum hosted by Social Security that gives all interested stakeholders an opportunity to share their unique insights on topics of particular interest to SSA early in the rulemaking process. The activities under the National Disability Forum supplement, but do not replace, the rule-making process followed by SSA under the Administrative Procedure Act.

These Forums serve as listening sessions, and bring public awareness to disability and retirement policy among stakeholders. Through these forums, we gain insight into how our policy affects the disability and retirement communities we serve, and the potential impact our policies may have in the future.

For more information, please visit our website at: *https://www.ssa.gov/ndf/.*

Mark Warshawsky,

Deputy Commissioner, Office of Retirement and Disability Policy.

[FR Doc. 2019–24833 Filed 11–14–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice:10942]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Malangatana: Mozambique Modern'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be exhibited in the exhibition ''Malangatana: Mozambique Modern,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Art Institute of Chicago, in Chicago, Illinois, from on or about March 22, 2020, until on or about July 5, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–24761 Filed 11–14–19; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1108 (Sub-No. 1X)]

The Blacklands Railroad—Discontinuance of Service Exemption—in Hunt, Delta, Hopkins, Franklin and Titus Counties, Tex.

On October 28, 2019, The Blacklands Railroad (BLR) filed a petition under 49 U.S.C. 10502 for exemption from the prior approval requirements of 49 U.S.C. 10903 to discontinue its operations over approximately 76 miles of rail line (the Line) in Hunt, Delta, Hopkins, Franklin, and Titus Counties, Tex.[1] In particular, BLR seeks authority to discontinue its operating rights over: (1) Approximately 31 miles of a line of railroad owned by the Northeast Texas Rural Rail Transportation District (NETEX) from milepost 524.0, located 6.2 miles west of Sulphur Springs, to milepost 555.0, near Greenville (also known as Simtrott); (2) an additional 34.59 miles of NETEX's line, from milepost 524.0 to milepost 489.41, at the eastern county line of Franklin County; and (3) trackage rights acquired by NETEX over a Union Pacific Railroad Company (UP) line, from milepost 489.41 to milepost 479.0 at Mt. Pleasant where BLR interchanges traffic with UP.[2] The Line traverses U.S. Postal Service Zip Codes 75455, 75493, 75457, 75478, 75482, 75401, 75433, 75428, and 75402.

According to BLR, its operations over the Line have resulted in significant financial losses over the last four years and there is no reasonable basis to believe profitability will improve in the near future. In addition, BLR states that, upon discontinuance, no customer on the Line will be left without common carrier service because NETEX is itself a Class III rail carrier on the Line.[3]

BLR states that it believes the Line does not contain any federally granted rights-of-way. BLR states that any documentation in its possession will be made available to those requesting it.

[1] BLR initially submitted its petition on October 25, 2019. In light of a supplement filed on October 28, 2019, that date is deemed the filing date of the petition for exemption.

[2] BLR states that it also leases directly from UP the segment between milepost 489.40 and milepost 481.5, and that these leased operations from UP are not the subject of the discontinuance authority sought in this proceeding. *See Blacklands R.R.—Lease & Operation Exemption—Union Pac. R.R.,* FD 34723 (STB served July 26, 2005).

[3] BLR states that NETEX sought and received authority to acquire and operate the Line as a common carrier in *Northeast Texas Rural Rail Transportation District—Purchase (Portion) Exemption—St. Louis Southwestern Railway Company,* FD 32841 (STB served Jan. 26, 1996) and *Northeast Texas Rural Rail Transportation District—Acquisition Exemption—Lines of Union Pacific Railroad Company,* FD 33892 (STB served Jul. 26, 2000).

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by February 14, 2020.

Because this is a discontinuance proceeding and not an abandonment proceeding, trail use/rail banking and public use conditions are not appropriate. Because there will be environmental review during any subsequent abandonment, this discontinuance does not require an environmental review. *See* 49 CFR 1105.6(c)(5), 1105.8(b).

Any offer of financial assistance (OFA) for subsidy under 49 CFR 1152.27(b)(2) will be due no later than 120 days after the filing of the petition for exemption, or 10 days after service of a decision granting the petition for exemption, whichever occurs sooner.[4] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer by November 25, 2019, indicating the intent to file an OFA for subsidy and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(1)(i).

All filings in response to this notice must refer to Docket No. AB 1108 (Sub-No. 1X) and must be filed with the Surface Transportation Board either via e-filing or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on BLR's representative, Thomas J. Litwiler, Fletcher & Sippel LLC, 29 N. Wacker Drive, Suite 800, Chicago, IL 60606. Replies to this petition are due on or before December 5, 2019.

Persons seeking further information concerning discontinuance procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment and discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Office of Environmental Analysis at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

Board decisions and notices are available at *www.stb.gov.*

[4] The filing fee for OFAs can be found at 49 CFR 1002.2(f)(25).

Decided: November 12, 2019.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Brendetta Jones,

Clearance Clerk.

[FR Doc. 2019–24828 Filed 11–14–19; 8:45 am]

BILLING CODE 4915–01–P

TENNESSEE VALLEY AUTHORITY

Environmental Impact Statement for Johnsonville Fossil Plant Ash Impoundment Closure

AGENCY: Tennessee Valley Authority.

ACTION: Notice of intent.

SUMMARY: The Tennessee Valley Authority (TVA) intends to prepare an Environmental Impact Statement (EIS) to address the potential environmental effects associated with the future management of coal combustion residuals (CCR) material at the Johnsonville Fossil Plant (JOF) located in Humphreys County, Tennessee. The purpose of this EIS is to address the disposition of Ash Pond 2 at JOF, to support the implementation of TVA's goal to eliminate all wet CCR storage at its coal plants by closing CCR surface impoundments across the TVA system, and to assist TVA in complying with the United States Environmental Protection Agency (EPA) CCR Rule and other applicable federal and state statutes and regulations. TVA will evaluate the closure of JOF Ash Pond 2 and will develop and evaluate various alternatives for closure including the No Action Alternative. One alternative identified by TVA is Closure-in-Place of Ash Pond 2. Another alternative is Closure-by-Removal of Ash Pond 2. TVA is considering four options for disposal of the CCR removed from Ash Pond 2, including transport and disposal of CCR in an existing offsite permitted landfill, transport and disposal of CCR to a new onsite landfill, transport and disposal of CCR to both an existing offsite permitted landfill and a new onsite landfill, and transport of CCR to a beneficial re-use processing facility to be processed for use in concrete and other building materials with any unusable CCR and excavated soil material going to an existing offsite or new onsite permitted landfill.

TVA has identified a potential location for a new onsite landfill. TVA has not selected a potential offsite landfill for disposal of CCR from JOF, and no specific provider of the beneficiation services or specific site at which a beneficial re-use processing facility would be constructed has been developed at this time. Therefore, impacts of these options for CCR disposal would be based on the most impactful or ''bounding'' characteristics of CCR transport to suitable existing landfills or to a beneficial re-use processing facility. Similarly, the potential effects of construction and operation of the beneficial re-use processing facility will be evaluated using 'bounding'' attributes obtained from candidate beneficiation vendors. Public comments are invited concerning both the scope of the review and environmental issues that should be addressed. No decisions have been made about the final disposition of CCR storage at COF Ash Pond 2.

DATES: Comments on the scope of the EIS must be received on or before December 20, 2019.

ADDRESSES: Written comments should be sent to W. Douglas White, NEPA Compliance Specialist, 400 W. Summit Hill Drive, WT 11B–K, Knoxville, TN 37902. Comments also may be submitted online at: *https://www.tva.gov/nepa* or by email to *wdwhite0@tva.gov.*

FOR FURTHER INFORMATION CONTACT: Other related questions should be sent to W. Douglas White, NEPA Compliance Specialist, Tennessee Valley Authority, at 865–632–2252 or *wdwhite0@tva.gov.*

SUPPLEMENTARY INFORMATION: This notice is provided in accordance with the Council on Environmental Quality's regulations (40 CFR parts 1500 to 1508) and TVA's procedures for implementing the National Environmental Policy Act (NEPA) and Section 106 of the National Historic Preservation Act (NHPA) and its implementing regulations (36 CFR part 800).

TVA Power System and CCR Management

TVA is a corporate agency and instrumentality of the United States created by and existing pursuant to the TVA Act of 1933 that provides electricity for business customers and local power distributors. TVA serves more than 9 million people in parts of seven southeastern states. TVA receives no taxpayer funding, deriving virtually all of its revenues from sales of electricity. In addition to operating and investing its revenues in its electric system, TVA provides flood control, navigation and land management for the Tennessee River system and assists local power companies and state and local governments with economic development and job creation.

JOF had ten coal-fired generating units that had a combined capacity of 1,254 megawatts. Units 5 through 10 ceased power generation in 2012 and

were retired on December 31, 2015. Units 1 through 4 ceased operation and were retired on December 31, 2017. While in operation, JOF consumed approximately 3.5 million tons of coal per year and produced approximately 7,195 million kilowatt-hours of electricity a year. CCR produced as a by-product to burning coal by the collective units was wet-sluiced to Ash Pond 2. It is estimated that approximately 4.6 million cubic yards (yd^3) of CCR material remains in JOF Ash Pond 2.

Historically, TVA has managed its CCR in wet impoundments or dry landfills. In July 2009, the TVA Board of Directors passed a resolution for staff to review TVA practices for storing CCRs at its generating facilities, including JOF, which resulted in a recommendation to convert the wet ash management system at JOF to a dry storage system. On April 17, 2015, the EPA published the final Disposal of CCR from Electric Utilities rule, also known as the CCR Rule.

In June 2016, TVA issued a Final Programmatic Environmental Impact Statement (PEIS) that analyzed methods for closing CCR impoundments at TVA fossil plants and identified specific screening and evaluation factors to help frame its evaluation of closures at its other facilities. A Record of Decision was released in July 2016 that would allow future environmental reviews of qualifying CCR impoundment closures to tier from the PEIS. The PEIS can be found at *www.tva.com/nepa.* This EIS is intended to tier from the 2016 PEIS to evaluate the closure alternatives for the JOF Ash Pond 2.

Alternatives

In addition to a No Action Alternative, this EIS will address alternatives that meet the purpose and need for the project. TVA plans to consider the following: (1) Closure-in-Place of Ash Pond 2, (2) Closure-by-Removal of Ash Pond 2 to an Existing Offsite Landfill, (3) Closure-by-Removal of Ash Pond 2 to a New Onsite Landfill, (4) Closure-by-Removal of Ash Pond 2 to an Existing Offsite and New Onsite Landfill, and (5) Closure-by-Removal of Ash Pond 2 to an Offsite Beneficial Re-use Processing Facility with unusable CCR and excavated soil material going to an existing offsite or new onsite permitted landfill.

No decision has been made about the final disposition of CCR storage at JOF. TVA is preparing this EIS to inform decision makers, other agencies, and the public about the potential for environmental impacts associated with the final disposition of CCR at JOF Ash Pond 2.

Proposed Resources and Issues to be Considered

This EIS will identify the purpose and need of the project and will contain descriptions of the existing environmental and socioeconomic resources within the area that could be affected by the management and final disposition of CCR at JOF. Evaluation of potential environmental impacts to these resources will include, but not be limited to, air quality, climate change, water quality, groundwater, geology and soils, aquatic and terrestrial ecology, threatened and endangered species, wetlands, floodplains, land use, noise, transportation, visual resources, historic and archaeological resources, solid and hazardous waste, safety, socioeconomic and environmental justice issues, and natural areas, parks, and recreation. The final range of issues to be addressed in the environmental review will be determined, in part, from scoping comments received. The preliminary identification of reasonable alternatives and environmental issues in this notice is not meant to be exhaustive or final.

Public Participation

TVA is committed to an open process and wants input from the community. The public is invited to submit comments on the scope of this EIS no later than the date identified in the **DATES** section of this notice. Federal, state and local agencies and Native American Tribes are also invited to provide comments.

After consideration of comments received during the scoping period, TVA will develop and distribute a scoping document that will summarize public and agency comments that were received and provide a schedule for completing the EIS process. Following analysis of the affected resources, TVA will prepare a draft EIS for public review and comment. A final decision on proceeding with the management and final disposal of CCR and closure of the Ash Pond 2 surface impoundment will be based on a number of factors including public comments, the conclusions of the EIS, the requirements of the CCR Rule, relevant state law requirements, engineering and risk evaluations, and financial considerations.

TVA expects to release the Draft EIS in late 2020. TVA anticipates holding a community meeting near JOF after releasing the Draft EIS. Meeting details will be posted on TVA's website and advertised in local media.

Authority: 40 CFR 1501.7.

M. Susan Smelley,

Director, Environmental Compliance and Operations.

[FR Doc. 2019–24830 Filed 11–14–19; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2019–0914]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves the recordkeeping requirement for owners/operators of aircraft issued a special airworthiness certificate in the light-sport aircraft category (SLSA) to keep the current status of applicable safety directives, and transfer these records with the aircraft at the time the aircraft is sold. The information to be collected is necessary to determine and ensure the SLSA aircraft is in a condition for safe flight prior to aircraft operation.

DATES: Written comments should be submitted by January 14, 2020.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field)

By email: Tanya Glines, tanya.glines@faa.gov

FOR FURTHER INFORMATION CONTACT: Tanya Glines by email at: *Tanya.glines@faa.gov;* phone: 801–257–5085.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality

of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0730.

Title: Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft.

Form Numbers: Aircraft maintenance records/logs.

Type of Review: Renewal of an information collection.

Background: Title 14 CFR, § 91.417(a)(2)(v) requires each registered owner or operator to retain records containing the current status of applicable safety directives including, for each, the method of compliance, the safety directive number and revision date. Additionally, if the safety directive involves recurring action, the time and date when the next action is required.

Recording this information and retaining these records is necessary to determine if unsafe conditions have been corrected on aircraft issued a special airworthiness certificate in the light-sport category (SLSA), which assists in ensuring that the SLSA aircraft is in a condition safe for flight prior to its operation within the national airspace.

Respondents include owners/operators of SLSA, aircraft mechanics, and LSA repairmen with a Maintenance rating. The records of SLSA safety directive compliance are retained by the aircraft owner/operator, who must keep the records for the life of the SLSA aircraft and transfer them to the new owner at the time the aircraft is sold. The burden estimates are based on the current number of registered SLA and a projected future growth rate.

Respondents: 2935 owners/operators of SLSA aircraft.

Frequency: On occasion.

Estimated Average Burden per Response: 2 Hours.

Estimated Total Annual Burden: 5870 hours annual industry burden.

Issued in Washington, DC, on November 12, 2019.

Tanya A. Glines,

Aviation Safety Inspector, Safety Standards, General Aviation Maintenance Branch (AFS–350).

[FR Doc. 2019–24829 Filed 11–14–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2019–0152]

Agency Information Collection Activities; Renewal of an Approved Information Collection Request: Designation of Agents, Motor Carriers, Brokers and Freight Forwarders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. FMCSA requests approval to renew an ICR titled ''Designation of Agents, Motor Carriers, Brokers and Freight Forwarders,'' which is used to provide registered motor carriers, property brokers, and freight forwarders a means of meeting process agent requirements.

DATES: We must receive your comments on or before December 16, 2019.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Docket Number FMCSA–2019–0152 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. e.t., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments, see the Public Participation heading below. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* and follow the online instructions for accessing the dockets, or go to the street address listed above.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Public Participation: The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the ''help'' section of the Federal eRulemaking Portal website. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket and will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Lorenzo Allen, Office of Registration and Safety Information, Department of Transportation, Federal Motor Carrier Safety Administration, West Building 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590. Telephone: 202–385–2465; email: *Lorenzo.allen@dot.gov.* Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

SUPPLEMENTARY INFORMATION:

Title: Designation of Agents, Motor Carriers, Brokers and Freight Forwarders.

OMB Control Number: 2126–0015.

Type of Request: Renewal of a currently-approved information collection.

Respondents: Motor carriers, freight forwarders and brokers.

Estimated Number of Respondents: 39,047.

Estimated Time per Response: 10 minutes.

Expiration Date: January 31, 2020.

Frequency of Response: On occasion. Form BOC–3 must be filed by all motor carriers, freight forwarders and brokers when the transportation entity first registers with the FMCSA. All brokers must make a designation for each State in which it has an office or in which contracts are written. Subsequent filings are made only if the motor carrier, broker or freight forwarder changes process agents.

Estimated Total Annual Burden: 6,508 hours [39,047 respondents × 10 minutes per response].

Background

The Secretary of Transportation (Secretary) is authorized to register motor carriers under the provisions of 49 U.S.C. 13902; freight forwarders under the provisions of 49 U.S.C. 13903; and property brokers under provisions of 49 U.S.C. 13904. These persons may conduct transportation services only if they are registered pursuant to 49 U.S.C. 13901. The Secretary delegated authority pertaining to these registration requirements to FMCSA in 49 CFR 1.73(a)(5).

Registered motor carriers, brokers and freight forwarders must designate an agent on whom service of notices in proceedings before the Secretary may be made (49 U.S.C. 13303). Registered motor carriers must also designate an agent for every State in which they operate and traverse in the United States during such operations, agents on whom process issued by a court may be served in actions brought against the registered motor carrier (49 U.S.C. 13304, 49 CFR 366.4T). Every broker shall make a designation for each State in which its offices are located or in which contracts are written (49 U.S.C. 13304, 49 CFR 366.4T). Regulations governing the designation of process agents are found at 49 CFR part 366. This designation is filed with FMCSA on Form BOC–3, ''Designation of Agents for Service of Process.'' The program decrease in annual burden hours from 18,395 to 6,508 is due to revised estimates of the number of respondents and responses. Previous estimates were based on 2014 data. Current estimates are based on May 2019 Motor Carrier Management Information System (MCMIS) and Safety Measurement System (SMS) data snapshots.

Public Comments Invited:

You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FMCSA to perform it's functions; (2) the accuracy of the estimated burden; (3) ways for the FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority delegated in 49 CFR 1.87 on: November 7, 2019.

Kelly Regal,

Associate Administrator for Office of Research and Information Technology.

[FR Doc. 2019–24791 Filed 11–14–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Bureau of Engraving and Printing

Environmental Impact Statement (EIS) for Construction and Operation of a Replacement Currency Production Facility at the Beltsville Agricultural Research Center, Prince George's County, MD

AGENCY: Bureau of Engraving and Printing, Department of the Treasury.

ACTION: Notice of Intent (NOI).

SUMMARY: The Department of the Treasury, Bureau of Engraving and Printing (BEP) announces its intent to prepare an Environmental Impact Statement (EIS) under the National Environmental Policy Act (NEPA) for the construction and operation of a replacement currency production facility.

DATES: Comments must be received by December 16, 2019.

ADDRESSES: Written comments may be mailed to: US Army Corps of Engineers, ATTN. Harvey Johnson, Programs and Project Management Division, 2 Hopkins Plaza, 10th Floor, Baltimore, MD 21201, or emailed to: *BEP-EIS@usace.army.mil.*

FOR FURTHER INFORMATION CONTACT: Harvey Johnson by email at *BEP-EIS@usace.army.mil.*

SUPPLEMENTARY INFORMATION: BEP is the federal agency tasked with developing and producing United States currency notes and other security documents. BEP currently operates production facilities in Washington, DC and in Fort Worth, Texas for this purpose. The Washington DC facility (DCF) is more than 100 years old and subject to sub-standard conditions that limit BEP's ability to modernize its production operations. These limitations include space, functional, and security deficiencies, in particular, segmented production processes and antiquated systems and equipment. From 2010 through 2017, BEP conducted various studies to evaluate alternative courses of action based on factors such as cost, location, and operational requirements. These investigations concluded that construction of a replacement production facility (vice renovation of the existing DCF) was the most appropriate and cost-effective course of action for BEP to modernize its currency production operations. A 2018 Government Accountability Office (GAO) review concurred with BEP's determination. Once operational, the new facility would phase out BEP's manufacturing operations at its existing Washington, DC facility (DCF); the main building in DC would be renovated for administrative purposes, and the Annex building would be returned to the General Services Administration (GSA). BEP is currently evaluating a potential site at the US Department of Agriculture (USDA) Beltsville Agricultural Research Center (BARC) for development of the new facility. The site's location would meet BEP's siting requirements for being accessible to commercial airports and interstate roadways, and for maintaining a reasonable commuting distance for its existing workforce in Washington, DC. A formal land transfer between BEP and USDA is pending further study of the site.

The EIS will analyze the potential impacts of siting a new BEP currency production facility at the BARC site. At a minimum, the EIS will analyze a No Action Alternative, the impacts of not constructing a replacement production facility at the BARC, and a Proposed Action Alternative. Other reasonable alternatives identified during conceptual design and the NEPA process for this proposed action will also be considered for evaluation in the EIS. Resource areas that will be analyzed in the EIS include: Land use, aesthetics, air quality, noise, geology and soils, water resources, biological resources, cultural resources, socioeconomics and environmental justice, traffic and transportation, utilities, and hazardous and toxic materials/waste. Mitigation measures will be presented in the EIS to reduce potential adverse effects.

The 2018 Farm Bill (Public Law 115–334) provided Congressional authorization for a land transfer between BEP and USDA. BEP is currently evaluating a potential site at the USDA's BARC on which to construct and operate the new facility. The BARC site is located in Beltsville, Prince George's County, Maryland on approximately 105 acres near the intersection of Poultry Road and Powder Mill Road. The site's location meets BEP's siting requirements for being accessible to commercial airports and interstate roadways, and for maintaining a reasonable commuting distance for its current workforce in Washington, DC. A formal land transfer between BEP and

USDA is pending further study of the site.

A replacement currency production facility would range in size from approximately 750,000 to 1 million square feet. Such a facility is needed to address the space and functional deficiencies of BEP's existing DCF located at 300 14th Street SW in Washington, DC. The proposed action would allow BEP to modernize and streamline its operational footprint within the National Capital Region (NCR). The proposed action would include siting and orientating the facility to meet specific operational, security, and safety standards, clearing and grading the site, placement of and connection to required utilities and infrastructure, and the phased construction and operation of the new facility. The phased operation of the proposed action would also include the transition or relocation of administrative and manufacturing personnel from BEP's existing DCF. However, the proposed action would not include structural changes to or disposition of any existing BEP facility assets within the NCR, including its current DCF. NEPA compliance for changes to or disposition of these assets will occur at a later date.

The EIS will analyze the potential impacts of siting this facility at the BARC site. At a minimum, the EIS will analyze a No Action Alternative, the impacts of not constructing a replacement production facility at the BARC, and a Proposed Action Alternative. Other reasonable alternatives identified during conceptual design and the NEPA process for BEP's proposed action will also be considered for evaluation in the EIS. Resource areas that will be analyzed in the EIS include: Land use, aesthetics, air quality, noise, geology and soils, water resources, biological resources, cultural resources, socioeconomics and environmental justice, traffic and transportation, utilities, and hazardous and toxic materials/waste. Mitigation measures will be presented in the EIS to reduce potential adverse effects.

The public is invited to participate in the scoping process. The scoping process begins with the publication of this Notice of Intent in the **Federal Register**and will last for 30 days. The scoping process will include a public scoping meeting, which is an opportunity for the public to receive information about the proposed action and assist BEP in identifying issues related to the proposed action. This meeting will take place near the BARC in Beltsville, Maryland; the specific details of the meeting will be announced in local media at least 2 weeks in advance. The public will also be invited to review and comment on the Draft EIS when it is available for review. Comments from the public will be considered before any decision is made regarding implementation of the proposed action.

David F. Eisner,

Assistant Secretary for Management.

[FR Doc. 2019–24802 Filed 11–14–19; 8:45 am]

BILLING CODE 4840–01–P

FEDERAL REGISTER

Vol. 84 Friday,
No. 221 November 15, 2019

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 409, 410, et al.
Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine; Final and Interim Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 409, 410, 411, 414, 415, 416, 418, 424, 425, 489, and 498

[CMS–1715–F and IFC]

RIN 0938–AT72

Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule and interim final rule.

SUMMARY: This major final rule addresses: Changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program quality reporting requirements; Medicaid Promoting Interoperability Program requirements for eligible professionals; the establishment of an ambulance data collection system; updates to the Quality Payment Program; Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations. In addition, we are issuing an interim final rule with comment period (IFC) to establish coding and payment for evaluation and management, observation and the provision of self-administered Esketamine to facilitate beneficiary access to care for treatment-resistant depression as efficiently as possible.

DATES:

Effective date: These regulations are effective on January 1, 2020.

Comment date: Comments will be accepted/considered ONLY on the Interim Rule ''Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine'' contained in section V. of the preamble of this document. To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1715–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1715–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1715–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Jamie Hermansen, (410) 786–2064, for any issues not identified below.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, conversion factor, and impacts.

Geri Mondowney, (410) 786–1172, or Tourette Jackson, (410) 786–4735, for issues related to malpractice RVUs and geographic practice cost indices (GPCIs).

Larry Chan, (410) 786–6864, or Geri Mondowney, (410) 786–1172, for issues related to potentially misvalued services under the PFS.

Lindsey Baldwin, (410) 786–1694, Emily Yoder, (410) 786–1804, or Patrick Sartini, (410) 786–9252, for issues related to telehealth services.

Pierre Yong, (410) 786–8896, or Lindsey Baldwin, (410) 786–1694, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs (OTPs).

Lindsey Baldwin, (410) 786–1694, for issues related to bundled payments under the PFS for substance use disorders.

Emily Yoder, (410) 786–1804, or Christiane LaBonte, (410) 786–7237, for issues related to the comment solicitation on opportunities for bundled payments under the PFS.

Regina Walker-Wren, (410) 786–9160, for issues related to physician supervision for physician assistant (PA) services and review and verification of medical record documentation.

Ann Marshall, (410) 786–3059, Emily Yoder, (410) 786–1804, Liane Grayson, (410) 786–6583, or Christiane LaBonte (410) 786–7237, for issues related to care management services.

Terry Simananda, (410) 786–8144, for issues related to interim final rule with comment period (payment for self-administered esketamine).

Kathy Bryant, (410) 786–3448, for issues related to coinsurance for colorectal cancer screening tests and global surgery data collection.

Pamela West, (410) 786–2302, for issues related to therapy services.

Ann Marshall, (410) 786–3059, Emily Yoder, (410) 786–1804, or Christiane LaBonte, (410) 786–7237, for issues related to payment for evaluation and management services.

Thomas Kessler, (410) 786–1991, for issues related to ambulance physician certification statement.

Felicia Eggleston, (410) 786–9287, or Amy Gruber, (410) 786–1542, for issues related to the ambulance fee schedule and the requirements related to the Medicare ground ambulance data collection system.

Linda Gousis, (410) 786–8616, for issues related to intensive cardiac rehabilitation.

David Koppel, (303) 844–2883, or Elizabeth LeBreton, (202) 615–3816, for issues related to the Medicaid Promoting Interoperability Program.

Fiona Larbi, (410) 786–7224, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality Measures.

Katie Mucklow, (410) 786–0537, or Diana Behrendt (410) 786–6192, for issues related to open payments.

Cheryl Gilbreath, (410) 786–5919, for issues related to home infusion therapy benefit.

Joseph Schultz, (410) 786–2656, for issues related to Medicare enrollment of opioid treatment programs, and enhancements to provider enrollment regulations concerning improper prescribing and patient harm.

Jacqueline Leach, (410) 786–4282, for issues related to Deferring to State Scope of Practice Requirements: Ambulatory Surgical Centers (ASC).

Mary Rossi-Coajou, (410) 786–6051, for issues related to Deferring to State Scope of Practice Requirements: Hospice.

1877AdvisoryOpinion@cms.hhs.gov, for issues related to Advisory Opinions on Application of the Physician Self-referral law.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Brittany LaCouture, (410) 786–0481, for inquiries related to Alternative Payment Models (APMs).

Patricia Taft, (410) 786–4561, for issues related to Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes Annual Update.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that website to view public comments.

Addenda Available Only Through the Internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2020 PFS final rule, refer to item CMS–1715–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact Jamie Hermansen at (410) 786–2064.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major final rule revises payment polices under the Medicare PFS and makes other policy changes, including provisions to implement certain provisions of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment, applicable to services furnished in CY 2020 and thereafter. In addition, this final rule includes provisions related to other payment policy changes that are addressed in section III. of this final rule.

To facilitate beneficiary access to treatment for treatment-resistant depression (TRD) as using esketamine, we are creating two new HCPCS G codes, G2082 and G2083, effective January 1, 2020 on an interim final basis. For 2020, we are establishing RVUs for these services that reflect the relative resource costs associated with the evaluation and management (E/M), observation and provision of the self-administered esketamine product.

1. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work; practice expense (PE); and malpractice (MP) expense. In addition, the statute requires that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this final rule, we are establishing RVUs for CY 2020 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes discussions and provisions regarding several other Medicare Part B payment policies, Medicare Shared Savings Program quality reporting requirements, Medicaid Promoting Interoperability Program requirements for eligible professionals, the establishment of a ground ambulance data collection system, updates to the Quality Payment Program, Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations. Specifically, this final rule addresses:

- Practice Expense RVUs (section II.B.)
- Malpractice RVUs (section II.C.)
- Geographic Practice Cost Indices (GPCIs) (section II.D.)
- Potentially Misvalued Services under the PFS (section II.E.)
- Telehealth Services (section II.F.)
- Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (section II.G.)
- Bundled Payments Under the PFS for Substance Use Disorders (section II.H.)
- Physician Supervision for Physician Assistant (PA) Services (section II.I.)
- Review and Verification of Medical Record Documentation (section II.J.)
- Care Management Services (section II.K.)
- Coinsurance for Colorectal Cancer Screening Tests (section II.L.)
- Therapy Services (section II.M.)
- Valuation of Specific Codes (section II.N.)
- Comment Solicitation on Opportunities for Bundled Payments under the PFS (section II.O.)
- Payment for Evaluation and Management (E/M) Services (section II.P.)
- Ambulance Coverage Services—Physician Certification Statement (section III.A.)
- Ambulance Fee Schedule—Medicare Ground Ambulance Data Collection System (section III.B.)
- Intensive Cardiac Rehabilitation (section III.C.)
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (section III.D.)
- Medicare Shared Savings Program Quality Measures (section III.E.)
- Open Payments (section III.F.)
- Home Infusion Therapy Benefit (section III.G.)
- Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm (section III.H.)
- Deferring to State Scope of Practice Requirements (section III.I.)
- Advisory Opinions on the Application of the Physician Self-Referral Law (section III.J.)

- Updates to the Quality Payment Program (section III.K.)
- Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes (section IV.)
- Interim Final Rule with Comment Period: Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS codes G2082 and G2083) (section V.)
- Collection of Information Requirements (section VI.)
- Regulatory Impact Analysis (section VII.)

2. Summary of Costs and Benefits

We have determined that this final rule is economically significant. For a detailed discussion of the economic impacts, *see* section VII. of this final rule.

II. Provisions of the Final Rule for the PFS

A. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, ''Payment for Physicians' Services.'' The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA '89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA '90). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this major final rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

1. Development of the RVUs

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding MP expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA of 1997) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA of 1997 provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in the November 2, 1998 final rule (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: the Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. These data sources are described in greater detail in the CY 2012 PFS final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some resource costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those specific facility resource costs is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and

published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA of 1997 amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' MP insurance premium data from all the states, the District of Columbia, and Puerto Rico. For more information on MP RVUs, *see* section II.C. of this final rule, Determination of Malpractice Relative Value Units.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed 5-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the 5-year reviews, beginning for CY 2009, CMS and the RUC identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, that require the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VII. of this final rule, the Regulatory Impact Analysis, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component. Please refer to the CY 2017 PFS final rule with comment period for a discussion of the last GPCI update (81 FR 80261 through 80270), and to the GPCI section of this current rule for the CY 2020 update.

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS' Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}$$

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia CF, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate CF for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work relative value units under the PFS and proposed changes to the PE

methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file called ''CY 2020 PFS Proposed Rule PE/HR'' on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2020, we have incorporated the available utilization data for two new specialties, each of which became a recognized Medicare specialty during 2018. These specialties are Medical Toxicology and Hematopoietic Cell Transplantation and Cellular Therapy. We proposed to use proxy PE/HR values for these new specialties, as there are no PPIS data for these specialties, by crosswalking the PE/HR as follows from specialties that furnish similar services in the Medicare claims data:

- Medical Toxicology from Emergency Medicine; and
- Hematopoietic Cell Transplantation and Cellular Therapy from Hematology/Oncology.

These updates are reflected in the ''CY 2020 PFS Final Rule PE/HR'' file available on the CMS website under the supporting data files for the CY 2020 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We did not receive any public comments on the use of the proposed PE/HR proxy values for Medical Toxicology and Hematopoietic Cell Transplantation and Cellular Therapy. Therefore, we are finalizing our PE/HR crosswalks as proposed.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00

(2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).

• Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

• Then, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file called ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to a RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we instead use the expected specialty that we identify on a list developed based on medical review and input from expert stakeholders. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 59283) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

For CY 2020, we proposed to clarify the expected specialty assignment for a series of cardiothoracic services. Prior to the creation of the expected specialty list for low volume services in CY 2018, we previously finalized through rulemaking a crosswalk to the thoracic surgery specialty for a series of cardiothoracic services that typically had fewer than 100 services reported each year (*see,* for example, the CY 2012 PFS final rule (76 FR 73188–73189)). However, we noted that for many of the affected codes, the expected specialty list for low volume services incorrectly listed a crosswalk to the cardiac surgery specialty instead of the thoracic surgery specialty. We proposed to update the expected specialty list to accurately reflect the previously finalized crosswalk to thoracic surgery for these services. The affected codes are shown in Table 1.

BILLING CODE 4120–01–P

TABLE 1: Updates to Expected Specialty

CPT Code	CY 2019 Expected Specialty	Updated CY 2020 Expected Specialty
33414	Cardiac Surgery	Thoracic Surgery
33468	Cardiac Surgery	Thoracic Surgery
33470	Cardiac Surgery	Thoracic Surgery
33471	Cardiac Surgery	Thoracic Surgery
33476	Cardiac Surgery	Thoracic Surgery
33478	Cardiac Surgery	Thoracic Surgery
33502	Cardiac Surgery	Thoracic Surgery
33503	Cardiac Surgery	Thoracic Surgery
33504	Cardiac Surgery	Thoracic Surgery
33505	Cardiac Surgery	Thoracic Surgery
33506	Cardiac Surgery	Thoracic Surgery
33507	Cardiac Surgery	Thoracic Surgery
33600	Cardiac Surgery	Thoracic Surgery
33602	Cardiac Surgery	Thoracic Surgery
33606	Cardiac Surgery	Thoracic Surgery
33608	Cardiac Surgery	Thoracic Surgery
33610	Cardiac Surgery	Thoracic Surgery
33611	Cardiac Surgery	Thoracic Surgery
33612	Cardiac Surgery	Thoracic Surgery
33615	Cardiac Surgery	Thoracic Surgery
33617	Cardiac Surgery	Thoracic Surgery
33619	Cardiac Surgery	Thoracic Surgery
33620	Cardiac Surgery	Thoracic Surgery
33621	Cardiac Surgery	Thoracic Surgery
33622	Cardiac Surgery	Thoracic Surgery
33645	Cardiac Surgery	Thoracic Surgery
33647	Cardiac Surgery	Thoracic Surgery
33660	Cardiac Surgery	Thoracic Surgery
33665	Cardiac Surgery	Thoracic Surgery
33670	Cardiac Surgery	Thoracic Surgery
33675	Cardiac Surgery	Thoracic Surgery
33676	Cardiac Surgery	Thoracic Surgery
33677	Cardiac Surgery	Thoracic Surgery
33684	Cardiac Surgery	Thoracic Surgery
33688	Cardiac Surgery	Thoracic Surgery
33690	Cardiac Surgery	Thoracic Surgery
33692	Cardiac Surgery	Thoracic Surgery
33694	Cardiac Surgery	Thoracic Surgery
33697	Cardiac Surgery	Thoracic Surgery
33702	Cardiac Surgery	Thoracic Surgery
33710	Cardiac Surgery	Thoracic Surgery
33720	Cardiac Surgery	Thoracic Surgery
33722	Cardiac Surgery	Thoracic Surgery
33724	Cardiac Surgery	Thoracic Surgery
33726	Cardiac Surgery	Thoracic Surgery
33730	Cardiac Surgery	Thoracic Surgery
33732	Cardiac Surgery	Thoracic Surgery
33735	Cardiac Surgery	Thoracic Surgery
33736	Cardiac Surgery	Thoracic Surgery
33737	Cardiac Surgery	Thoracic Surgery
33750	Cardiac Surgery	Thoracic Surgery
33755	Cardiac Surgery	Thoracic Surgery
33762	Cardiac Surgery	Thoracic Surgery
33764	Cardiac Surgery	Thoracic Surgery
33766	Cardiac Surgery	Thoracic Surgery
33767	Cardiac Surgery	Thoracic Surgery
33768	Cardiac Surgery	Thoracic Surgery
33770	Cardiac Surgery	Thoracic Surgery
33771	Cardiac Surgery	Thoracic Surgery
33774	Cardiac Surgery	Thoracic Surgery
33775	Cardiac Surgery	Thoracic Surgery
33776	Cardiac Surgery	Thoracic Surgery
33777	Cardiac Surgery	Thoracic Surgery
33778	Cardiac Surgery	Thoracic Surgery
33779	Cardiac Surgery	Thoracic Surgery
33780	Cardiac Surgery	Thoracic Surgery
33781	Cardiac Surgery	Thoracic Surgery
33782	Cardiac Surgery	Thoracic Surgery
33783	Cardiac Surgery	Thoracic Surgery
33786	Cardiac Surgery	Thoracic Surgery
33788	Cardiac Surgery	Thoracic Surgery
33800	Cardiac Surgery	Thoracic Surgery
33802	Cardiac Surgery	Thoracic Surgery
33803	Cardiac Surgery	Thoracic Surgery
33813	Cardiac Surgery	Thoracic Surgery
33814	Cardiac Surgery	Thoracic Surgery
33820	Cardiac Surgery	Thoracic Surgery
33822	Cardiac Surgery	Thoracic Surgery
33824	Cardiac Surgery	Thoracic Surgery
33840	Cardiac Surgery	Thoracic Surgery
33845	Cardiac Surgery	Thoracic Surgery
33851	Cardiac Surgery	Thoracic Surgery
33852	Cardiac Surgery	Thoracic Surgery
33853	Cardiac Surgery	Thoracic Surgery
33917	Cardiac Surgery	Thoracic Surgery
33920	Cardiac Surgery	Thoracic Surgery
33922	Cardiac Surgery	Thoracic Surgery
33924	Cardiac Surgery	Thoracic Surgery
33925	Cardiac Surgery	Thoracic Surgery
33926	Cardiac Surgery	Thoracic Surgery
35182	Cardiac Surgery	Thoracic Surgery

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We note that the cardiac surgery and thoracic surgery specialties are similar to one another, sharing the same PE/HR data for PE valuation and nearly

identical MP risk factors for MP valuation. As a result, we noted that we did not anticipate the proposal having a discernible effect on the valuation of the codes listed above. The complete list of expected specialty assignments for individual low volume services, including the assignments for the codes identified in Table 1, is available on our website under downloads for the CY 2020 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We received public comments on the proposed updates to the expected specialty list. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that CMS had indicated that the expected specialty would be updated to include a column specifying if a service was identified as a low volume service for CY 2020, indicating if the service-level override was being applied for CY 2020. However, commenters noted that this additional column did not appear in the download version and asked for additional information.

Response: We thank the commenters for identifying this missing information and we apologize for the technical oversight that caused this information not to be displayed for the proposed rule. We will include this additional column in the public use files released with the final rule.

Comment: Several commenters disagreed with the CMS proposal to update the expected specialty list to accurately reflect the previously finalized crosswalk to thoracic surgery for these services. Commenters stated that when the expected specialty list was developed, the affected specialties specifically selected the cardiac surgery specialty for these codes. Commenters also stated that, for nearly all of the applicable codes, cardiac surgery was the dominant provider in the 2018 Medicare claims data. Commenters acknowledged that the MP risk factor for both cardiac surgery and thoracic surgery is naturally very similar, but still asked that CMS assign the codes listed in Table 1 to the cardiac surgery specialty.

Response: As we stated in the proposed rule, we did not propose to assign the codes listed in Table 1 to the cardiac surgery specialty. Instead, we proposed to update the incorrect documentation in our expected specialty list to accurately reflect the previously finalized crosswalk to thoracic surgery for these services. The previously finalized assignment of the cardiac specialty to these services has been in place since the CY 2012 rule cycle, and we believe that the expected specialty list should be updated to reflect the correct specialty assignment.

Comment: Several commenters disagreed with the CMS methodology used to determine low volume service status; that is, codes that have fewer than 100 allowed services in the non-modified 3-year average of Medicare claims data. Commenters stated that utilization frequencies are adjusted in the RUC database for certain codes based on the CPT modifiers that were appended to the code to ensure that certain services are not over- or underweighted, such as changes made for bilateral modifier 50, post-op only modifier 55 and anesthesia modifiers QK, QX and QY. Commenters stated that CMS does not discount the utilization when determining what constitutes a low volume service and instead uses the non-modified 3-year service count for this criterion. Commenters stated that this could lead to double-counting and overestimating utilization for the purposes of determining low volume status, and requested that CMS use discounted utilization for this purpose.

Response: We disagree that it would be more accurate to use a discounted form of utilization to determine low volume status. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use claims data to determine which codes are low volume for the coming year, defining ''low volume'' as those that had fewer than 100 allowed services in the Medicare claims data. We did not finalize a policy to discount this utilization and we do not believe that it would be more accurate to do so, as a service is still performed even if a payment discount is applied to its billing. More importantly, we did not make any proposals concerning the methodology to determine what constitute a low volume service in the proposed rule, and therefore, we are not finalizing any changes to this methodology.

Comment: One commenter provided a list of 112 additional codes that the commenter stated were low volume procedures, with an expected specialty for each code. The commenter recommended that CMS append this list to the anticipated specialty assignment for low volume services. Another commenter stated that gastroenterologists do not perform CPT code 96571 on a current basis, and recommended that CMS remove gastroenterology as the expected specialty for this code.

Response: We appreciate the list of additional services identified by the commenter. As we have stated in previous rulemaking (82 FR 52982), we consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. In reviewing the submitted list of 112 additional codes, we noted that they generally fell into two categories—codes with a restricted coverage status code (''R'') or codes that exceed 100 services in the claims data, and therefore, did not meet our criteria for low volume status. We are finalizing the addition of these 112 codes to the low volume services list with the recommended expected specialty; however, we caution that many of these codes will continue to have utilization too high to meet the criteria for expected specialty assignment. We are adding these codes to the list in the interest of maintaining payment stability, such that, if they were to fall below 100 annual services at a future date, then an expected specialty would be assigned. We do not have indirect PE data for two of the specialties on the recommended list, and as a result we are substituting the established PE/HR crosswalk for these specialties. (The full list of all established PE/HR crosswalks is available on our website under downloads for the CY 2020 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*) The two affected specialties are Interventional Cardiology (crosswalked to Cardiology) and Surgical Oncology (crosswalked to General Surgery). We are also finalizing a change to the expected specialty for CPT code 96571 in response to the information supplied by the commenter, which we are changing to Pulmonary Disease to match the dominant specialty in the claims data. The complete list of additional updates to the low volume services list is detailed in Table 2.

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TABLE 2: Additional Updates to Expected Specialty in Response to Comments

CPT Code	Updated CY 2020 Expected Specialty
11950	Plastic And Reconstructive Surgery
11951	Plastic And Reconstructive Surgery
11952	Plastic And Reconstructive Surgery
11954	Plastic And Reconstructive Surgery
11976	Obstetrics/Gynecology
15130	Plastic And Reconstructive Surgery
15775	Plastic And Reconstructive Surgery
15776	Plastic And Reconstructive Surgery
15935	Plastic And Reconstructive Surgery
15945	Plastic And Reconstructive Surgery
21325	Otolaryngology
21330	Otolaryngology
21630	Plastic And Reconstructive Surgery
22862	Neurosurgery
22865	Neurosurgery
23333	Orthopedic Surgery
25449	Orthopedic Surgery
26842	Orthopedic Surgery
27140	Orthopedic Surgery
28261	Orthopedic Surgery
30400	Plastic And Reconstructive Surgery
30410	Plastic And Reconstructive Surgery
30430	Plastic And Reconstructive Surgery
30435	Plastic And Reconstructive Surgery
30450	Plastic And Reconstructive Surgery
31551	Otolaryngology
31552	Otolaryngology
31553	Otolaryngology
31554	Otolaryngology
31592	Otolaryngology
31717	Pulmonary Disease
32486	Thoracic Surgery
32491	Thoracic Surgery
32900	Thoracic Surgery
33203	Thoracic Surgery
33320	Thoracic Surgery
33927	Thoracic Surgery
33935	Cardiac Surgery
34708	Vascular Surgery
34833	Vascular Surgery
36456	Pediatrics
38115	General Surgery
40819	Oral Surgery
40842	Plastic And Reconstructive Surgery
40843	Plastic And Reconstructive Surgery

CPT Code	Updated CY 2020 Expected Specialty
40844	Plastic And Reconstructive Surgery
41822	Plastic And Reconstructive Surgery
41823	Plastic And Reconstructive Surgery
41828	Plastic And Reconstructive Surgery
41830	Plastic And Reconstructive Surgery
41872	Plastic And Reconstructive Surgery
42340	Otolaryngology
42892	Otolaryngology
43211	Gastroenterology
43217	Gastroenterology
43284	General Surgery
43285	General Surgery
43286	General Surgery
43338	Thoracic Surgery
43846	General Surgery
44100	Gastroenterology
44370	Gastroenterology
44401	Gastroenterology
44680	General Surgery
45562	General Surgery
48520	General Surgery
48548	General Surgery
49426	General Surgery
49427	Interventional Radiology
50010	Urology
50400	Urology
50580	Urology
50705	Interventional Radiology
50953	Urology
54411	Urology
57296	Obstetrics/Gynecology
57513	Obstetrics/Gynecology
58152	Obstetrics/Gynecology
58275	Obstetrics/Gynecology
58544	Obstetrics/Gynecology
58674	Obstetrics/Gynecology
59840	Obstetrics/Gynecology
59841	Obstetrics/Gynecology
59850	Obstetrics/Gynecology
59851	Obstetrics/Gynecology
59852	Obstetrics/Gynecology
59855	Obstetrics/Gynecology
59856	Obstetrics/Gynecology
59857	Obstetrics/Gynecology
59866	Obstetrics/Gynecology

CPT Code	Updated CY 2020 Expected Specialty
61533	Neurosurgery
61537	Neurosurgery
64913	Hand Surgery
66770	Ophthalmology
69300	Otolaryngology
69666	Otolaryngology
69806	Otolaryngology
72159	Diagnostic Radiology
73225	Diagnostic Radiology
77610	Radiation Oncology
77615	Radiation Oncology
77620	General Surgery
77763	Radiation Oncology
90473	Pediatrics
90474	Pediatrics
90955	Nephrology
93592	Cardiology
96571	Pulmonary Disease
96931	Dermatology
96932	Dermatology
96934	Dermatology
96936	Dermatology
99155	Emergency Medicine

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Comment: Several commenters stated that the non-facility PE RVUs for CPT code 55874 (*Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed*) are projected to decrease 13 percent for CY 2020, which the commenter believed to be attributed to the current specialty mix utilizing the code. The commenters stated that the projected decrease for CY 2020 was due to CMS using the first year of actual claims data, which had a different ratio of the urology and radiation oncology specialties than in the previously projected utilization crosswalk. The commenters requested that CMS address the proposed decreases for CPT code 55874 in the final rule.

Response: We agree with the commenters that the proposed decreases for CPT code 55874 were due to changes in the specialty mix, as the code shifted from projected utilization to reported claims data. However, we do not agree with the commenters that there is a need to address the valuation of this code, as we believe that it is important to use actual claims data as opposed to utilization projections once the data for new codes has become available. The specialty mix on reported claims will necessarily be more accurate than the utilization projections created in advance before claims data exists. We also note that the specialty mix associated with CPT code 55874 in the claims data is unrelated to the low volume list or the assignment of an expected specialty.

Comment: A commenter stated that CPT codes 33271 (*Insertion of subcutaneous implantable defibrillator electrode*) and 33273 (*Repositioning of previously implanted subcutaneous implantable defibrillator electrode*) are low volume service codes that are proposed to have a service-level override to the anticipated specialty of cardiology. The commenter supported this expected specialty assignment.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing our proposal to update the expected specialty list to accurately reflect the previously finalized crosswalk to thoracic surgery for these services. We are also finalizing the updates to the expected specialty list detailed above in Table 2; we reiterate again that we do not anticipate this finalized proposal having a discernible effect on the valuation of the codes in the table due to the similarity between the cardiac surgery and thoracic surgery specialties.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file called ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators

for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (*Note:* For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the proposed aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 2.

TABLE 3: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

- Crosswalk *certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- Physical *therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (*Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*).
- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time

accordingly. Table 4 details the manner in which the modifiers are applied.

TABLE 4: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- Work *RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate) ∧ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.
usage = variable, *see* discussion below in this final rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, *see* discussion below in this final rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Stakeholders have often suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce the equipment utilization rate based on these recommendations. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items. However, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system.

Comment: A commenter stated that they disagreed with the 90 percent utilization metric for CT and MRI equipment, as the commenter did not believe it to be realistic in a typical outpatient imaging setting, but the commenter recognized that the percentage is dictated by statute. The commenter stated that the 90 percent equipment usage assumption for CT and MRI is inconsistent with actual imaging center practice and ignores scheduling in the ''real world,'' such as lunch and other mandated breaks, complicated patients, and downtime for maintenance and quality control. The commenter stated that to achieve a 90 percent utilization rate under ideal conditions would require two employees per unit; one doing pre-service tasks while the other is setting up the machine as opposed to assumptions of one CT or MRI technologist per scanner.

Response: We disagree with the commenters regarding the equipment time assigned to highly technical equipment such as CT or MRI machines. We continue to believe that certain highly technical pieces of equipment

and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure and are typically available for other patients even when one member of clinical staff may be occupied with a preservice or postservice task related to the procedure. For a more detailed description of this topic, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67639 through 67640).

Comment: One commenter stated that most ophthalmology diagnostic equipment is in use far less than 50 percent of the time. The commenter indicated that they had developed a survey instrument that asked ophthalmic technicians to provide time usage estimates for the 16 most-utilized pieces of diagnostic testing equipment. The commenter stated that their preliminary survey results produced a utilization rate of 22 percent, much lower than the 50 percent assumption currently used by CMS. The commenter suggested that CMS should work with the RUC to do a robust survey to help determine a more valid utilization rate, including the possibility of specialty-specific equipment utilization rates. The commenter also requested a meeting to discuss what options CMS would find acceptable in undertaking their own survey for ophthalmology services.

Response: We are always looking for more accurate information to improve our PE methodology. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items, and we will review any information that the RUC's PE subcommittee or other stakeholders are willing to submit through the public comment process. We concur with the commenter that a wide-ranging survey or similar study designed to address the subject of equipment utilization rates would be an appropriate tool to investigate this subject in further detail. At the moment, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system. We welcome further submission of data that illustrates an alternative rate.

Maintenance: This factor for maintenance was finalized in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We do not believe that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we noted that we did not believe that we have sufficient information at present to do so. We continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

Comment: A commenter stated that they continue to believe that maintenance costs for imaging equipment are much higher than the current 5 percent assumption. The commenter stated that the maintenance costs for an MRI unit include servicing the scanner itself plus replacing cryogens for a cost well in excess of 5 percent even using CMS' low assumptions of MRI and CT room cost.

Response: As detailed above, we continue to believe that the current 5 percent maintenance factor likely understates the true cost of maintaining some equipment and overstates the maintenance costs for other equipment. We continue at this time to lack publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining maintenance factor. We remind readers that when we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale.

Interest Rate: In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (*see* 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). We did not propose any changes to these interest rates for CY 2020. The Interest rates are listed in Table 5.

TABLE 5: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

Comment: A commenter stated that they did not support the continued use of the 2012 SBA maximum interest rates, which the commenter stated are significantly lower than the 2019 rates. The commenter stated that CMS should also update the interest rates used to calculate PE RVUs for such items based on current SBA data.

Response: We appreciate the additional information regarding SBA

maximum interest rates from the commenter. However, we did not propose any changes to these interest rates for CY 2020; we will consider potential changes to the interest rates used in the equipment cost per minute calculation for possible future rulemaking.

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2020 direct PE input public use files, which are available on the CMS website under downloads for the CY 2020 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640–67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and postservice periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS.'' Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values.

We also finalized standard times for clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902) at 4 minutes for ''Accession specimen/prepare for examination'', 0.5 minutes for ''Assemble and deliver slides with paperwork to pathologists'', 0.5 minutes for ''Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation'', 1 minute for ''Clean room/equipment following procedure'', 1 minute for ''Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste'', and 1 minute for ''Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).'' We do not believe these activities would be dependent on number of blocks or batch size, and we believe that these values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (''Review patient clinical extant information and questionnaire'') in the preservice period, and CA014 (''Confirm order, protocol exam'') in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 and 59464).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties

developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2020, we are continuing to display two versions of the Labor Task Detail public use file: One version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2020 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Comment: A commenter wrote to express their concerns with the manner in which data was displayed in the Proposed CY 2020 Direct PE Refinements table in the proposed rule (84 FR 40623–40666), specifically the common refinements to equipment time. The commenter stated that nearly 64 percent of the total PE refinements were related to equipment, and 59 percent of these refinements were listed as ''E15: Refined equipment time to conform to changes in clinical labor time.'' The commenter stated that they did not agree that these are separate refinements; rather, they are the formulaic result of the applying refinements to the clinical labor time. The commenter stated that including these instances as refinements adds a large quantity of rows to the PE refinement table and gives the impression that there are major inaccuracies in the RUC PE recommendations. The commenter provided an example of a single clinical labor refinement to a code family creating 32 rows of subsequent equipment refinements, and contended that articulating these edits was not necessary as they do not reflect either an error or a policy discrepancy with the RUC. The commenter requested that CMS no longer include refinements based on ''E15: Refined equipment time to conform to changes in clinical labor time'' in the refinement table of the proposed rule.

Response: We agree with the commenter that these equipment time refinements generated in response to clinical labor time refinements are indeed the result of applying standard equipment time formulas, and they do not reflect errors in the equipment recommendations or policy discrepancies with the RUC. We also agree that these refinements add a significant number of rows to the table of direct PE refinements. However, we disagree with the commenter on the subject of whether these constitute separate refinements, and we believe that it is important to publish the specific equipment times that we are proposing (or finalizing in the case of the final rule) when they differ from the recommended values. We include the direct cost change in dollars resulting from our PE refinements on the aforementioned table, and if we were to avoid including these equipment refinements, it would not always be clear what effect they were having on the direct costs for the procedure. For example, a modest reduction of a few minutes in clinical labor time can result in a substantial decrease in direct costs for procedures that employ highly expensive equipment. We believe that it is more important to provide additional transparency regarding the changes in direct costs resulting from our equipment time refinements so that the public can better comment on our proposals, as opposed to limiting the total number of printed equipment refinements.

However, we agree with the commenter that the information displayed in the table of direct PE refinements can be confusing and overwhelming, and we believe that it could potentially be provided to the public in a more useful fashion. For this CY PFS 2020 final rule, we will separate out the ''E15: Refined equipment time to conform to changes in clinical labor time'' direct PE refinements and print them in a separate table of refinements. We believe that this will help to address the issues raised by the commenter while also retaining all of the data included in previous rules. We refer readers to Table 28 in section II.N. of this final rule, the Valuation of Specific Codes section, for additional details.

b. Equipment Recommendations for Scope Systems

During our routine reviews of direct PE input recommendations, we have regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. Some of the scopes include video systems bundled into the equipment item, some of them include scope accessories as part of their price, and some of them are standalone scopes with no other equipment included. It is not always clear which equipment items related to scopes fall into which of these categories. We have also frequently found anomalies in the equipment recommendations, with equipment items that consist of a scope and video system bundle recommended, along with a separate scope video system. Based on our review, the variations do not appear to be consistent with the different code descriptions.

To promote appropriate relativity among the services and facilitate the transparency of our review process, during the review of the recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope, the associated video system, and any scope accessories that might be typical as distinct equipment items for each code. Under this approach, we proposed standalone prices for each scope, and separate prices for the video systems and accessories that are used with scopes.

(1) Scope Equipment

Beginning in the CY 2017 PFS proposed rule (81 FR 46176 through 46177), we proposed standardizing refinements to the way scopes have been defined in the direct PE input database. We believe that there are four general types of scopes: Non-video scopes; flexible scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the scope video systems, while the non-video scopes would not. The flexible scopes can be further divided into diagnostic (or non-channeled) and therapeutic (or channeled) scopes. We proposed to identify for each anatomical application: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. We proposed to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services. We planned to propose input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes for CY 2017 that made use of scopes, along with updated prices for the equipment items related to scopes utilized by these services. We did not propose to apply these policies

to codes with inputs reviewed prior to CY 2017. We also solicited comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we noted we could consider proposing to apply to other codes in future rulemaking. We did not finalize price increases for a series of other scopes and scope accessories, as the invoices submitted for these components indicated that they are different forms of equipment with different product IDs and different prices. We did not receive any data to indicate that the equipment on the newly submitted invoices was more typical in its use than the equipment that we were currently using for pricing.

We did not make further changes to existing scope equipment in CY 2017 to allow the RUC's PE Subcommittee the opportunity to provide feedback. However, we believed there was some miscommunication on this point, as the RUC's PE Subcommittee workgroup that was created to address scope systems stated that no further action was required following the finalization of our proposal. Therefore, we made further proposals in the CY 2018 PFS proposed rule (82 FR 33961 through 33962) to continue clarifying scope equipment inputs, and sought comments regarding the new set of scope proposals. We considered creating a single scope equipment code for each of the five categories detailed in this rule: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We stated our belief that the variation between these scopes was not significant enough to warrant maintaining these distinctions, and we believed that creating and pricing a single scope equipment code for each category would help provide additional clarity. We sought public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

After considering the comments on the CY 2018 PFS proposed rule, we did not finalize our proposal to create and price a single scope equipment code for each of the five categories previously identified. Instead, we supported the recommendation from the commenters to create scope equipment codes on a per-specialty basis for six categories of scopes as applicable, including the addition of a new sixth category of multi-channeled flexible video scopes. Our goal was to create an administratively simple scheme that would be easier to maintain and help to reduce administrative burden. In 2018, the RUC convened a Scope Equipment Reorganization Workgroup to incorporate feedback from expert stakeholders with the intention of making recommendations to us on scope organization and scope pricing. Since the workgroup was not convened in time to submit recommendations for the CY 2019 PFS rulemaking cycle, we delayed proposals for any further changes to scope equipment until CY 2020 in order to incorporate the feedback from the aforementioned workgroup.

(2) Scope Video System

We proposed in the CY 2017 PFS proposed rule (81 FR 46176 through 46177) to define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system was the ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' equipment item (ES031), which we proposed to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we proposed to use for this re-pricing. In response to comments, we finalized the addition of a digital capture device to the endoscopy video system (ES031) in the CY 2017 PFS final rule (81 FR 80188). We finalized our proposal to price the system at $33,391, based on component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, and $1,750 for the cart. In the CY 2018 PFS final rule (82 FR 52991 through 52993), we outlined, but did not finalize, a proposal to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures. We also described a proposal to increase the price of the scope video system by $1,000 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.). With the addition of the LED light (equipment code EQ382 at a price of $1,915), the updated total price of the scope video system would be set at $36,306.

We did not finalize this updated pricing to the scope video system in CY 2018, but we did propose and finalize the updated pricing for CY 2019 to $36,306 along with changing the name of the ES031 equipment item to ''scope video system (monitor, processor, digital capture, cart, printer, LED light)'' to reflect the fact that the use of the ES031 scope video system is not limited to endoscopy procedures.

(3) Scope Accessories

We understand that there may be other accessories associated with the use of scopes. We finalized a proposal in the CY 2017 PFS final rule (81 FR 80188) to separately price any scope accessories outside the use of the scope video system, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

(4) Scope Proposals for CY 2020

The Scope Equipment Reorganization Workgroup organized by the RUC submitted detailed recommendations to CMS for consideration in the CY 2020 rule cycle, describing 23 different types of scope equipment, the HCPCS codes associated with each scope type, and a series of invoices for scope pricing. We appreciate the information provided by the workgroup and continue to welcome additional comments and feedback from stakeholders. Based on the recommendations from the workgroup, we proposed to establish 23 new scope equipment codes as detailed in Table 6.

TABLE 6: Proposed CY 2020 New Scope Equipment Codes

CMS Code	Proposed Scope Equipment Description	Proposed Price	Number of Invoices
ES070	rigid scope, cystoscopy		0
ES071	rigid scope, hysteroscopy		0
ES072	rigid scope, otoscopy		0
ES073	rigid scope, nasal/sinus endoscopy		0
ES074	rigid scope, proctosigmoidoscopy		0
ES075	rigid scope, laryngoscopy	$3,966.08	5
ES076	rigid scope, colposcopy	$14,500.00	1
ES077	non-channeled flexible digital scope, hysteroscopy		0
ES078	non-channeled flexible digital scope, nasopharyngoscopy		0
ES079	non-channeled flexible digital scope, bronchoscopy		0
ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51	7
ES081	channeled flexible digital scope, cystoscopy		0
ES082	channeled flexible digital scope, hysteroscopy		0
ES083	channeled flexible digital scope, bronchoscopy		0
ES084	channeled flexible digital scope, laryngoscopy	$18,694.39	5
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00	1
ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81	6
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)		0
ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35	5
ES089	multi-channeled flexible digital scope, ileoscopy		0
ES090	multi-channeled flexible digital scope, pouchoscopy		0
ES091	ultrasound digital scope, endoscopic ultrasound		0
ES092	non-video flexible scope, laryngoscopy	$5,078.04	4

We note that we did not receive invoices for many of the new scope equipment items. There also was some inconsistency in the workgroup recommendations regarding the non-channeled flexible digital scope, laryngoscopy (ES080) equipment item and the non-video flexible scope, laryngoscopy (ES092) equipment item. These scopes were listed as a single equipment item in some of the workgroup materials and listed as separate equipment items in other materials. We proposed to establish them as separate equipment items based on the submitted invoices, which demonstrated that these were two different types of scopes with distinct price points of approximately $17,000 and $5,000 respectively.

We noted a similar issue with the submitted invoices for the rigid scope, laryngoscopy (ES075) equipment item. Among the eight total invoices, five of them were clustered around a price point of approximately $4,000 while the other three invoices had prices of roughly $15,000 apiece. The invoices indicated that these prices came from two distinct types of equipment, and as a result we proposed to consider these items separately. We proposed to use the initial five invoices to establish a proposed price of $3,966.08 for the rigid scope, laryngoscopy (ES075) equipment item. We noted that this is a close match for the current price of $3,178.08 used by the endoscope, rigid, laryngoscopy (ES010) equipment, which is the closest equivalent scope equipment. We also noted that the other three invoices appear to describe a type of stroboscopy system rather than a scope, and they have an average price of $14,737. This is a reasonably close match for the price of our current stroboscoby system (ES065) equipment, which has a CY 2020 price of $17,950.28 as it transitions to a final CY 2022 destination price of $16,843.87 (see the 4-year pricing transition of the market-based supply and equipment pricing update discussed later in this section for more information). We stated that we believe that these invoices reinforce the value established by the market-based pricing update for the stroboscoby system carried out last year, and we did not propose to update the price of the ES065 equipment. We also noted that we were open to feedback from stakeholders if they believe it would be more accurate to assign a price of $14,737 to the stroboscoby system based on these invoice submissions, as opposed to maintaining the current pricing transition to a CY 2022 price of $16,843.87.

For the eight new scope equipment items where we received submitted invoices for pricing, we proposed to replace the existing scopes with the new scope equipment. We noted that we received recommendations from the RUC's scope workgroup regarding which HCPCS codes make use of the new scope equipment items, and we proposed to make this scope replacement for approximately 100 HCPCS codes in total (see Table 7).

TABLE 7: Proposed Scope Equipment Replacement

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
31505	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31510	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31511	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31512	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31515	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31525	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31570	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
56820	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
56821	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57420	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57421	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57452	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57454	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57455	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57456	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57460	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57461	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
31551	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31552	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31553	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31554	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31574	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31575	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31579	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31580	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31584	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31587	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31591	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31592	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
92612*	ES027	video system, FEES (scope, camera, light source, image capture, monitor, printer, cart)	$21,675.00	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
92614*	ES028	video system, FEESST (scope, sensory stimulator, camera, light source, image capture, monitor, printer, cart)	$25,420.25	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
92616*	ES028	video system, FEESST (scope, sensory stimulator, camera,	$25,420.25	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
		light source, image capture, monitor, printer, cart)				
31572	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31573	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31576	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31577	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31578	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
45330	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45331	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45332	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45333	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45334	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45335	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45338	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45340	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45346	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
G0104	ES021	fiberscope, flexible, sigmoidoscopy	$10,976.97	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45378	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45379	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45380	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45381	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45382	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
45384	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45385	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45386	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45388	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45398	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
G0105	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
G0121	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44388	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44389	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44390	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44391	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44392	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44394	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44401	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44404	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44405	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
43197	ES026	video add-on camera system w-monitor (endoscopy)	$9,514.13	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43198	ES026	video add-on camera system w-monitor (endoscopy)	$9,514.13	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43200	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43201	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43202	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43206	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43213	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
43215	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43216	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43217	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43220	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43226	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43227	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43229	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
31590	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31300	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31360	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31365	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31367	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31368	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31370	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31375	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31380	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31382	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31390	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31395	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31400	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31420	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04

* See the discussion that follows.

In all but three cases (as identified with an asterisk (*) in Table 7), we proposed for the new scope equipment item to replace the existing scope with the identical amount of equipment time. For CPT codes 92612 (*Flexible endoscopic evaluation of swallowing by cine or video recording*), 92614 (*Flexible endoscopic evaluation, laryngeal sensory testing by cine or video recording*), and 92616 (*Flexible endoscopic evaluation of swallowing and laryngeal sensory testing by cine or video recording*), we noted the current scopes in use are the FEES video system

(ES027) and the FEESST video system (ES028). Since we proposed the use of a non-channeled flexible digital scope that requires a corresponding scope video system, we also proposed to add the ES080 equipment at the same equipment time to these three procedures rather than replacing the ES027 and ES028 equipment. In all other cases, we proposed to replace the current scope equipment listed in Table 7 with the new scope equipment, while maintaining the same amount of equipment time.

We identified inconsistencies with the workgroup recommendations for a small number of HCPCS codes. CPT code 45350 (*Sigmoidoscopy, flexible; with band ligation(s) (e.g., hemorrhoids)*) was recommended to include a multi-channeled flexible digital scope, flexible sigmoidoscopy (ES085); however, we noted that this CPT code does not include any scopes among its current direct PE inputs. CPT code 31595 was recommended to include a non-channeled flexible digital scope, laryngoscopy (ES080) but it no longer exists as a CPT code after having been deleted for CY 2019. CPT code 43232 (*Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/ biopsy(s)*) was recommended to include a multi-channeled flexible digital scope, esophagoscopy (ES088), but it does not include a scope amongst its direct PE inputs any longer following clarification from the same workgroup recommendations that CPT code 43232 is never performed in the nonfacility setting. In all three of these cases, we did not propose to add one of the new scope equipment items to these procedures.

We noted that we did not receive pricing information along with the workgroup recommendations for the other 15 new scope equipment items. Therefore, we proposed to establish new equipment codes for these scopes as detailed in Table 6. However, we noted that due to a lack of pricing information, we did not propose to replace existing scope equipment with the new equipment items as we did for the other eight new scope equipment items for CY 2020. We welcomed additional feedback from stakeholders regarding the pricing of these scope equipment items, especially the submission of detailed invoices with pricing data. We proposed to transition the scopes for which we did have pricing information over to the new equipment items for CY 2020, and we noted that we looked forward to engaging with stakeholders to assist in pricing and then transitioning the remaining scopes in future rulemaking.

We received public comments on our scope equipment proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they appreciated the proposal of the recommended 23 new scope equipment codes and the proposed pricing of 8 of those new scope equipment codes. Commenters also stated that they appreciated the proposal of scope replacements for 100 CPT codes as recommended by the RUC utilizing the 8 scopes that CMS was able to price. One commenter encouraged CMS to continue to work with the RUC workgroup and other stakeholders to obtain detailed invoices for the scopes for which it did not have pricing data to assist in the correct pricing and transition of these equipment items.

Response: We appreciate the support for our proposals from the commenters. We welcome the submission of additional pricing data from the RUC scope workgroup and other stakeholders regarding the pricing of the remaining scope equipment items.

Comment: One commenter stated that they appreciated the recognition of the existing specialized equipment that is required in addition to the proposed scope equipment, and they supported the proposal to add ES080 and retain ES027 or ES028 at the same equipment time for CPT codes 92612, 92614, and 92616.

Response: We appreciate the support for our proposals from the commenter.

Comment: Several commenters stated it was their understanding that additional scope pricing information submitted now would be considered for the CY 2021 PFS proposed rule. These commenters asked for clarification that the CPT codes impacted by any scope proposals for CY 2021 will be outlined in a table just as the impacted codes for CY 2020 were outlined in Table 7, so that they will be subject to stakeholder review and comment prior to implementation.

Response: As we stated in the proposed rule, we welcome additional feedback from stakeholders regarding the pricing of these remaining scope equipment items, especially the submission of detailed invoices with pricing data. Any future proposals that we make regarding scope equipment will be subject to notice and comment rulemaking, including displaying information in a table similar Table 7, if it would be appropriate to do so.

Comment: A commenter stated that they had identified inconsistencies with the scope workgroup recommendations for a small number of HCPCS codes. The commenter stated that CPT code 45350 (*Sigmoidoscopy, flexible; with band ligation(s) (e.g., hemorrhoids)*) was recommended by the workgroup to include a multi-channeled flexible digital scope, flexible sigmoidoscopy (ES085); however, CMS noted in the proposed rule that this CPT code does not include any scopes among its current direct PE inputs. The commenter stated that all codes in the flexible sigmoidoscopy family require a flexible sigmoidoscope in order to perform the procedure, and therefore, the commenter requested that CMS add the ES085 scope equipment to CPT code 45350.

Response: We appreciate the feedback from the commenter in pointing out this inconsistency in the direct PE inputs for CPT code 45350. Based on the information supplied by the commenter, we are finalizing the addition of the ES085 scope equipment to CPT code 45350. We are finalizing an equipment time of 59 minutes based on the use of our standard equipment time formula for scopes.

Comment: A commenter requested that the ''rigid scope, hysteroscopy'' (ES071) equipment be updated to read ''rigid scope, channeled, hysteroscopy'' and that the hysteroscopy codes (that is, CPT codes 58555, 58562, 58565) be valued with ES071. The commenter submitted an invoice with pricing information associated with the ES071 scope equipment.

Response: We appreciate the submission of an invoice from the commenter for use in pricing the ES071 scope. Based on the information provided by the commenter, we are finalizing a change in the name of the ES071 scope from ''rigid scope, hysteroscopy'' to ''rigid scope, channeled, hysteroscopy.'' We are also finalizing a price of $6,795 for the ES071 scope based on the pricing data supplied by the commenter, and we are finalizing the replacement of the existing ''endoscope, rigid, hysteroscopy'' (ES009) scope with the new ES071 scope equipment. The CPT codes affected by this replacement are CPT codes 58555, 58562, and 58565 as identified by the commenter, as well as CPT code 58563 which is the only other code that previously employed the ES009 scope. These scope replacements are summarized below in Table 9.

Comment: One commenter provided a series of invoices for different types of rigid scopes in response to the comment solicitation.

Response: We appreciate the submission of additional invoices from the commenter. Based on the

information included in these invoices, we are finalizing prices for three scopes that did not previously have pricing data. We are finalizing a price of $2,333.98 for the ''rigid scope, otoscopy'' (ES072) equipment, a price of $3,004.75 for the ''rigid scope, nasal/sinus endoscopy'' (ES073) equipment, and a price of $21,923.425 for the ''non-channeled flexible digital scope, nasopharyngoscopy'' (ES078) equipment. We are not finalizing the replacement of any of the old scope equipment codes with these three new scope equipment items for CY 2020, as the commenter did not identify the HCPCS codes in which this replacement would take place. We will consider additional scope pricing information for these three scope equipment codes, including the HCPCS codes in which they would typically be employed, as part of the CY 2021 PFS proposed rule.

The commenter also provided five new invoices for the pricing of the ''non-video flexible scope, laryngoscopy'' (ES092) equipment. These five invoices had an average price of $5,105.97, which was nearly identical to our proposed price of $5,078.04 for the ES092 scope. We believe that these invoices reinforce the accuracy of the proposed pricing. We are finalizing an increase in the price of the ES092 scope to $5,105.97, which will slightly increase the direct costs for the 14 HCPCS codes containing this scope listed above in Table 7.

Comment: Several commenters sent a series of additional invoices, and recommended crosswalks from existing equipment codes to the proposed equipment codes to ensure that the equipment currently listed for GI endoscopy procedures was appropriately attributed to the correct new scopes. Although the commenters did not provide information to update any of the proposed scope equipment prices, the commenters did clarify that several of the new scope equipment items which lacked proposed prices in fact shared the same current scope equipment codes as other new scope equipment items that did have proposed pricing. For example, CMS proposed to replace the ''videoscope, gastroscopy'' (ES034) scope equipment with the new ''multi-channeled flexible digital scope, esophagoscopy'' (ES088) scope equipment. The commenters clarified that this same ES034 equipment, when used in additional CPT codes, would be replaced by either the ''multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy'' (ES087) or the ''multi-channeled flexible digital scope, ileoscopy'' (ES089) equipment items, all of which should share the same proposed price of $34,585.35. The commenter also explained that the same ''Video Sigmoidoscope'' (ES043) equipment which CMS proposed to replace with the ''multi-channeled flexible digital scope, pouchoscopy'' (ES090) new scope equipment would, in additional CPT codes, be replaced by the new ''multi-channeled flexible digital scope, flexible sigmoidoscopy'' (ES085) scope equipment, and that both ES085 and ES090 should share the same proposed price of $19,308.56. Finally, the commenter also stated that the new ''ultrasound digital scope, endoscopic ultrasound'' (ES091) equipment item would only be used in the facility setting, and that none of the HCPCS codes that included this scope contained direct PE inputs.

Response: We appreciate the submission of additional invoices and the clarification of the relationship between the former scope equipment codes and the newly created scope equipment codes. After considering this additional information supplied by the commenters, we are updating Table 8 of CY 2020 new scope equipment codes.

TABLE 8: Final CY 2020 New Scope Equipment Codes

CMS Code	Proposed Scope Equipment Description	Proposed Price	Finalized Price
ES070	rigid scope, cystoscopy		
ES071	rigid scope, channeled, hysteroscopy		$6,795.00
ES072	rigid scope, otoscopy		$2,333.98
ES073	rigid scope, nasal/sinus endoscopy		$3,004.75
ES074	rigid scope, proctosigmoidoscopy		
ES075	rigid scope, laryngoscopy	$3,966.08	$3,966.08
ES076	rigid scope, colposcopy	$14,500.00	$14,500.00
ES077	non-channeled flexible digital scope, hysteroscopy		
ES078	non-channeled flexible digital scope, nasopharyngoscopy		$21,923.43
ES079	non-channeled flexible digital scope, bronchoscopy		
ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51	$21,485.51
ES081	channeled flexible digital scope, cystoscopy		
ES082	channeled flexible digital scope, hysteroscopy		
ES083	channeled flexible digital scope, bronchoscopy		
ES084	channeled flexible digital scope, laryngoscopy	$18,694.39	$18,694.39
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00	$17,360.00
ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81	$38,058.81
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)		$34,585.35
ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35	$34,585.35
ES089	multi-channeled flexible digital scope, ileoscopy		$34,585.35
ES090	multi-channeled flexible digital scope, pouchoscopy		$17,360.00
ES091	ultrasound digital scope, endoscopic ultrasound		$0.00
ES092	non-video flexible scope, laryngoscopy	$5,078.04	$5,105.97

We note again that we are not finalizing changes to the pricing of the group of new scope equipment codes with previously proposed prices, aside from the minor increase in the price of the ES092 equipment, only newly pricing several scopes that previously lacked pricing, and extending proposed pricing such that the ES087 and ES089 scopes share the same price with the ES088 scope, and the ES090 scope shares the same price with the ES085 scope. The new scope equipment codes ES087, ES088, and ES089 all share the same price because they are replacing the same current scope equipment code (ES034), and similarly the new ES085 and ES090 scope equipment codes share the same price because they are both replacing the same current scope equipment code (ES043). There are 21 HCPCS codes which are affected by the new scope replacements; these codes are detailed in Table 9.

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TABLE 9: Additional Scope Equipment Replacement in Response to Comments

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
58555	ES009	endoscope, rigid, hysteroscopy	$6,295.62	ES071	rigid scope, channeled, hysteroscopy	$6,795.00
58562	ES009	endoscope, rigid, hysteroscopy	$6,295.62	ES071	rigid scope, channeled, hysteroscopy	$6,795.00
58563	ES009	endoscope, rigid, hysteroscopy	$6,295.62	ES071	rigid scope, channeled, hysteroscopy	$6,795.00
58565	ES009	endoscope, rigid, hysteroscopy	$6,295.62	ES071	rigid scope, channeled, hysteroscopy	$6,795.00
43235	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43236	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43239	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43245	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43247	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43248	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43249	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43250	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43251	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43252	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
43255	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy	$34,585.35

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
					gastroscopy duodenoscopy (EGD)	
43270	ES034	videoscope, gastroscopy	$27,582.01	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
44380	ES034	videoscope, gastroscopy	$27,582.01	ES089	multi-channeled flexible digital scope, ileoscopy	$34,585.35
44381	ES034	videoscope, gastroscopy	$27,582.01	ES089	multi-channeled flexible digital scope, ileoscopy	$34,585.35
44382	ES034	videoscope, gastroscopy	$27,582.01	ES089	multi-channeled flexible digital scope, ileoscopy	$34,585.35
44385	ES043	Video Sigmoidoscope	$19,308.56	ES090	multi-channeled flexible digital scope, pouchoscopy	$17,360.00
44386	ES043	Video Sigmoidoscope	$19,308.56	ES090	multi-channeled flexible digital scope, pouchoscopy	$17,360.00

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Although we are updating the scope equipment pricing for CY 2020 such that the ES087 and ES089 scopes share the same price with the ES088 scope, and the ES090 scope shares the same price with the ES085 scope, we do not mean to suggest that these scopes that share pricing are identical with one another. We are assigning the same price to these scopes because they are replacing the same current scope equipment codes, and because we do not have individual pricing information for them at the moment. We are open to the submission of additional invoices in future rule cycles to establish individual pricing for these scopes, and we continue to welcome more data to help identify pricing for the remaining 7 scope equipment codes that still lack invoices.

After consideration of the public comments, we are finalizing pricing for the new scope equipment as detailed above in Table 8. We are also finalizing the scope equipment replacements as detailed in Tables 7 and 9.

c. Technical Corrections To Direct PE Input Database and Supporting Files

Subsequent to the publication of the CY 2019 PFS final rule, stakeholders alerted us to several clerical inconsistencies in the direct PE database. We proposed to correct these inconsistencies as described below and reflected in the CY 2020 proposed direct PE input database displayed on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2020, we proposed to address the following inconsistencies:

- The RUC's Scope Equipment Reorganization Workgroup recommended deletion of the non-facility inputs for CPT codes 43231 (*Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination*) and 43232 (*Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)*). The gastroenterology specialty societies stated that these services are never performed in the non-facility setting. After our own review of these services, we agreed with the workgroup's recommendation, and we proposed to remove the non-facility direct PE inputs for these two CPT codes.
- In rulemaking for CY 2018, we reviewed a series of CPT codes describing nasal sinus endoscopy surgeries. At that time, we sought comments on whether the broader family of nasal sinus endoscopy surgery services should be subject to the special rules for multiple endoscopic procedures instead of the standard multiple procedure payment reduction. We received very few comments in response to our solicitation. In the CY 2018 PFS final rule (82 FR 53043), we indicated that we would continue to explore this option for future rulemaking. We proposed to apply the special rule for multiple endoscopic procedures to this family of codes beginning in CY 2020. We noted this proposal would treat this group of CPT codes consistently with other similar endoscopic procedures when codes within the CPT code family are billed together with another endoscopy service in the same family. Similar to other similar endoscopic procedure code families, we proposed that CPT code 31231 (*Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)*) would be the base procedure for the remainder of nasal sinus endoscopies. The codes affected by the proposal are detailed in Table 10.

TABLE 10: Proposed Nasal Sinus Endoscopy Codes Subject to Special Rules for Multiple Endoscopic Procedures

CPT Code	Short Descriptor
31231	Nasal endoscopy dx
31233	Nasal/sinus endoscopy dx
31235	Nasal/sinus endoscopy dx
31237	Nasal/sinus endoscopy surg
31238	Nasal/sinus endoscopy surg
31239	Nasal/sinus endoscopy surg
31240	Nasal/sinus endoscopy surg
31241	Nsl/sins ndsc w/artery lig
31253	Nsl/sins ndsc total
31254	Nsl/sins ndsc w/prtl ethmdct
31255	Nsl/sins ndsc w/tot ethmdct
31256	Exploration maxillary sinus
31257	Nsl/sins ndsc tot w/sphendt
31259	Nsl/sins ndsc sphn tiss rmvl
31267	Endoscopy maxillary sinus
31276	Nsl/sins ndsc frnt tiss rmvl
31287	Nasal/sinus endoscopy surg
31288	Nasal/sinus endoscopy surg
31290	Nasal/sinus endoscopy surg
31291	Nasal/sinus endoscopy surg
31292	Nasal/sinus endoscopy surg
31293	Nasal/sinus endoscopy surg
31294	Nasal/sinus endoscopy surg
31295	Sinus endo w/balloon dil
31296	Sinus endo w/balloon dil
31297	Sinus endo w/balloon dil
31298	Nsl/sins ndsc w/sins dilat

Special rules for multiple endoscopic procedures would apply if any of the procedures listed in Table 10 are billed together for the same patient on the same day. We apply the multiple endoscopy payment rules to a code family before ranking the family with other procedures performed on the same day (for example, if multiple endoscopies in the same family are reported on the same day as endoscopies in another family, or on the same day as a non-endoscopic procedure). If an endoscopic procedure is reported together with its base procedure, we do not pay separately for the base procedure. Payment for the base procedure is included in the payment for the other endoscopy. For additional information about the payment adjustment under the special rule for multiple endoscopic services, we refer readers to the CY 1992 PFS final rule where this policy was established (56 FR 59515) and to Public Law 100–04, Medicare Claims Processing Manual, Chapter 23 (available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c23.pdf*).

We received public comments on the proposed technical corrections to the direct PE input database and supporting files. The following is a summary of the comments we received and our responses.

Comment: One commenter agreed with the RUC workgroup's recommendation and the CMS proposal to remove the non-facility direct PE inputs from CPT code 43231 and 43232.

Response: We appreciate the support for our proposals from the commenter.

Comment: One commenter stated that the proposed approach for nasal sinus endoscopy procedure better reflects the work RVU associated with the different levels of sinus endoscopy procedures and stated their support for this payment change. The commenter requested clarification regarding the application of the bilateral adjustment in conjunction with the special rules for multiple endoscopic procedures. The commenter stated that it was their understanding that if the CPT code is reported as a bilateral procedure and is reported with other procedure codes on the same day, the guidance is to apply the bilateral adjustment before applying any form of multiple procedure rules.

Response: The special rule for multiple endoscopic procedures has been described correctly in general terms by the commenter, although we encourage readers once again to refer to the CY 1992 PFS final rule where this policy was established (56 FR 59515) and to Public Law 100–04, Medicare Claims Processing Manual, Chapter 23. This manual text states that special rules for multiple endoscopic procedures apply if the procedure is billed with another endoscopy in the same family (*i.e.,* another endoscopy that has the same base procedure). The base procedure for each code with this indicator is identified in the endoscopic base code field. In these situations, we apply the multiple endoscopy rules to a family before ranking the family with other procedures performed on the same day (for example, if multiple endoscopies in the same family are reported on the same day as endoscopies in another family or on the same day as a non-endoscopic procedure). If an endoscopic procedure is reported with only its base procedure, we do not pay separately for the base procedure. Payment for the base procedure is included in the payment for the other endoscopy.

Comment: A commenter requested clarification regarding the proposal to apply the special rule for multiple endoscopic procedures to the family of codes listed in Table 10. The commenter stated that it was their understanding that that the diagnostic endoscopy described by CPT code 31231 is included in the valuation of all of the surgical procedure codes on the list (for example, CPT codes 31254, 31256, 31276, etc.), and therefore, CPT Code 31231 would not be billed on the same side that any nasal endoscopic surgical code(s) are performed. However, the commenter stated that it was their understanding that CPT code 31231 could be billed for one side of the nose if it was the only procedure performed and there was no surgical intervention on that side. Assuming that this interpretation was correct, the commenter stated that they supported the application of the special rules for endoscopy to the nasal endoscopy family.

Response: We reiterate that the special rule for multiple endoscopic procedures has been described correctly in general terms by the commenter, although we encourage readers once again to refer to the CY 1992 PFS final rule where this policy was established (56 FR 59515) and to Public Law 100–

04, Medicare Claims Processing Manual, Chapter 23. We encourage stakeholders to contact their local Medicare Administrative Contractor (MAC) for information regarding proper billing instructions for CPT code 31231.

Comment: One commenter stated that they were troubled by the proposal to apply the multiple endoscopy payment methodology to the CPT codes included in Table 10 without further clarification in the regulatory language or the Medicare Carriers Manual about the number of multiple procedure modifiers CMS can append to one claim. The commenter questioned whether these 27 codes will be assigned a multiple procedure indicator of ''3'' and if that would override the prior multiple procedure indicator of ''4''. The commenter stated that they did not support the application of multiple endoscopy payment rules if CMS intended to assign reductions for both multiple endoscopy and multiple procedures, as application of both payment rules would result in inappropriate reductions to this set of services.

Response: In response to the commenter's question, only one multiple procedure indicator can be applied to each HCPCS code. We also clarify that our proposal would assign a multiple procedure indicator of ''3'' to all of the codes listed in Table 10 aside from CPT code 31231, which would be the endoscopic ''base code'' and would be assigned a multiple procedure indicator of ''2''. We also note that none of these codes previously contained a multiple procedure indicator of ''4'', which is associated with certain diagnostic imaging services. We encourage readers once again to refer to the CY 1992 PFS final rule where this policy was established (56 FR 59515) and to Pub. 100–04, Medicare Claims Processing Manual, Chapter 23.

Comment: One commenter stated that although they recognized that by including the nasal endoscopy family among the codes using the special rule for multiple endoscopies, CMS may be trying to harmonize endoscopic procedures, and they stated that the unique situation surrounding the nasal endoscopy code family should prohibit the application of this special rule. The commenter stated that the nasal endoscopy code family differed significantly from colonoscopy procedures in that there is not uniformity across the sites of service where these sinus procedures are performed, since these services could be performed in both the facility and non-facility settings. The commenter stated that applying the special rules for multiple endoscopic procedures to this group would result in a significant inappropriate reduction in the value of the secondary and subsequent nasal surgical codes performed on the same patient on the same day when performed in the office setting, and the commenter stated that they opposed the application of the special rules for multiple endoscopies to the nasal endoscopy family in the non-facility setting.

Response: We disagree that this nasal endoscopy code family differs significantly from other colonoscopy families where the special rule for multiple endoscopic procedures has long been in place. Although the commenter stated that the nasal endoscopy codes were unique in the sense that they could be performed in both the facility and non-facility settings, and that the base code for the family, CPT code 31231, is typically an office-based procedure with significant PE built into the code, we note in response that there are many other groups of codes which utilize the special rule for multiple endoscopic procedures and are also performed in both the facility and non-facility settings. These include CPT codes 31573–31579 (base CPT code 31575), CPT codes 43220–43229 (base CPT code 43220), CPT codes 44389–44394 (base CPT code 44388), and CPT codes 45303–45320 (base CPT code 45300). There are dozens of these codes which can be performed in both the facility and non-facility settings, many of them with significant PE inputs built into their non-facility valuation. In light of this evidence, we disagree with the commenter that there is a unique situation regarding the nasal endoscopy family of codes.

Comment: Several commenters requested that CMS utilize the RUC-recommended direct PE inputs to publish PE relative value units for CPT code 90460, which was reviewed by the RUC in October 2009. Rather than finalize the RUC recommendations, CMS crosswalked CPT code 90460 from CPT code 90471, which is crosswalked from CPT code 96372 (formerly CPT code 90772 and then 90782). Commenters stated that the recent measles crisis spotlights the importance of immunization administration being appropriately valued, and that the crosswalk from CPT code 96372 to codes CPT codes 90471/90460 has brought about a 60 percent reduction in PE RVUs. Commenters stated that CMS typically only uses a crosswalk for work values, not PE values, and requested that CMS disconnect the codes after the initial crosswalk so that changes to the source code no longer affect the crosswalked code. One commenter stated that CMS was proposing to reduce the non-facility PE RVUs for CPT code 90471 from 0.29 in 2019 to 0.22 in 2020, and while this may appear to be a relatively small change in RVUs, if finalized it would reduce the national unadjusted payment for CPT code 90471 (and consequently the payment rates for HCPCS codes G0008 and G0009) by 15 percent.

Response: We appreciate the feedback from the commenters and note that we finalized the crosswalks associated with CPT code 90460 in the CY 2011 final rule (75 FR 73306). However, we note that we are separately addressing the valuation of HCPCS codes G0008, G0009, and G0010 in the codes valuation section of this rule.

We also received comments regarding a variety of subjects about which we did not make proposals for CY 2020. These included comments regarding the proper specialty employed to determine indirect cost factors for home PT/INR monitoring services and the application of the multiple procedure payment reduction to physical therapist services. We will take the feedback from the commenters on these subjects into consideration for future rulemaking.

After consideration of the public comments, we are finalizing the proposal to remove the non-facility direct PE inputs from CPT code 43231 and 43232. We are also finalizing the proposal to apply the special rule for multiple endoscopic procedures to the family of codes listed in Table 10 without refinement.

d. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2020, we proposed the following price updates for existing direct PE inputs.

We proposed to update the price of one supply and one equipment item in response to the public submission of invoices. As these pricing updates were each part of the formal review for a code family, we proposed that the new pricing take effect for CY 2020 for these items instead of being phased in over 4 years.

We also proposed to update the name of the EP001 equipment item from ''DNA/digital image analyzer (ACIS)'' to ''DNA/Digital Image Analyzer'' due to

clarification from stakeholders regarding the typical use of this equipment.

(1) Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

As part of our authority under section 1848(c)(2)(M) of the Act, we initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004–2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

The StrategyGen team of researchers, attorneys, physicians, and health policy experts conducted a market research study of the supply and equipment items currently used in the PFS direct PE input database. Resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. StrategyGen conducted secondary market research on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey).
- Physician panel validation of market research results, prioritized by total spending (Physician Panel).
- The General Services Administration system (GSA).
- An aggregate health system buyers database with discounted prices (Buyers).
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors).
- **Federal Register**, current DPEI data, historical proposed and final rules prior to CY 2018, and other resources; that is, AMA RUC reports (References).

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology based on the following rules in hierarchical order considering both data representativeness and reliability.

(1) If the market share, as well as the sample size, for the top three commercial products were available, the weighted average price (weighted by percent market share) was the reported RP. Commercial price, as a weighted average of market share, represents a more robust estimate for each piece of equipment and a more precise reference for the RP.

(2) If no data were available for commercial products, the current CMS prices were used as the RP.

GSA prices were not used to calculate the StrategyGen recommended prices, due to our concern that the GSA system curtails the number and type of suppliers whose products may be accessed on the GSA Advantage website, and that the GSA prices may often be lower than prices that are available to non-governmental purchasers. After reviewing the StrategyGen report, we proposed to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen.

StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicated that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. This cumulative stable pricing for medical equipment and supplies appears similar to the pricing impacts of non-medical technology advancements where some historically high-priced equipment (that is, desktop PCs) has been increasingly substituted with current technology (that is, laptops and tablets) at similar or lower price points. However, while there were no statistically significant differences in pricing at the aggregate level, medical specialties would experience increases or decreases in their Medicare payments if CMS were to adopt the pricing updates recommended by StrategyGen. At the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing, although we note that codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs, as required by section 1848(c)(7) of the Act. The phase-in requirement limits the maximum RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

We believe that it is important to make use of the most current information available for supply and equipment pricing instead of continuing to rely on pricing information that is more than a decade old. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, in the CY 2019 PFS proposed rule we proposed to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. This approach is consistent with how we have previously incorporated significant new data into the calculation of PE RVUs, such as the 4-year transition period finalized in CY 2007 PFS final rule with comment period when changing to the ''bottom-up'' PE methodology (71 FR 69641). This transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

We proposed to implement this phase-in over 4 years so that supply and equipment values transition smoothly from the prices we currently include to the final updated prices in CY 2022. We proposed to implement this pricing transition such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices

fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 11.

TABLE 11: Example of Direct PE Pricing Transition

Current Price	$100	
Final Price	$200	
Year 1 (CY 2019) Price	$125	1/4 difference between $100 and $200
Year 2 (CY 2020) Price	$150	1/3 difference between $125 and $200
Year 3 (CY 2021) Price	$175	1/2 difference between $150 and $200
Final (CY 2022) Price	$200	

For new supply and equipment codes for which we establish prices during the transition years (CYs 2019, 2020 and 2021) based on the public submission of invoices, we proposed to fully implement those prices with no transition since there are no current prices for these supply and equipment items. These new supply and equipment codes would immediately be priced at their newly established values. We also proposed that, for existing supply and equipment codes, when we establish prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a HCPCS code includes a review of pricing of the supplies and equipment included in the code. When we find that the price on the submitted invoice is typical for the item in question, we believe it would be appropriate to finalize the new pricing immediately along with any other revisions we adopt for the code valuation.

For existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which we establish prices based on invoices submitted by the public, we proposed to implement the established invoice price as the updated price and to phase in the new price over the remaining years of the proposed 4-year pricing transition. During the proposed transition period, where price changes for supplies and equipment are adopted without a formal review of the HCPCS codes that include them (as is the case for the many updated prices we proposed to phase in over the 4-year transition period), we believe it is important to include them in the remaining transition toward the updated price. We also proposed to phase in any updated pricing we establish during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. We would implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period. Our proposal was intended to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply and equipment items (meaning that these items are included in 100 or more codes).

We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer timeframe will allow more opportunities for public comment and submission of additional, applicable data. We welcomed feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

We received many comments regarding the market-based supply and equipment pricing proposal following the publication of the CY 2019 PFS proposed rule. For a full discussion of these comments, we direct readers to the CY 2019 PFS final rule (83 FR 59475–59480). In each instance in which a commenter raised questions about the accuracy of a supply or equipment code's recommended price, the StrategyGen contractor conducted further research on the item and its price with special attention to ensuring that the recommended price was based on the correct item in question and the clarified unit of measure. Based on the commenters' requests, the StrategyGen contractor conducted an extensive examination of the pricing of any supply or equipment items that any commenter identified as requiring additional review. Invoices submitted by multiple commenters were greatly appreciated and ensured that medical equipment and supplies were re-examined and clarified. Multiple researchers reviewed these specified supply and equipment codes for accuracy and proper pricing. In most cases, the contractor also reached out to a team of nurses and their physician panel to further validate the accuracy of the data and pricing information. In some cases, the pricing for individual items needed further clarification due to a lack of information or due to significant variation in packaged items. After consideration of the comments and this additional price research, we updated the recommended prices for approximately 70 supply and equipment codes identified by the commenters. Table 9 in the CY 2019 PFS final rule lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing (83 FR 59479–59480).

After consideration of the public comments, we finalized our proposals associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing. We continue to believe that implementing the proposed updated prices with a 4-year phase-in will improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. We continue to welcome feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

For CY 2020, we received invoice submissions for approximately 30 supply and equipment codes from stakeholders as part of the second year of the market-based supply and

equipment pricing update. These invoices were reviewed by the StrategyGen contractor and the submitted invoices were used in many cases to supplement the pricing originally proposed for the CY 2019 PFS rule cycle. The contractor reviewed the invoices, as well as prior data for the relevant supply/equipment codes to make sure the item in the invoice was representative of the supply/equipment item in question and aligned with past research. Based on this research, we proposed to update the prices of the supply and equipment items listed in Table 9 of the CY 2020 PFS proposed rule.

For most supply and equipment items, there was an alignment between the research carried out by the StrategyGen contractor and the submitted invoice. The updated CY 2020 pricing was calculated using an average between the previous market research and the newly submitted invoices in these cases. In some cases the submitted invoices were not representative of market prices, such as for the centrifuge with rotor (EP007) equipment item where the invoice price of $8,563 appeared to be an outlier. We did not use the invoices to calculate our pricing recommendation in these situations and instead continued to rely on our prior pricing data. In other instances, such as for the kit, probe, cryoablation, prostate (Galil-Endocare) (SA099) supply item, our research indicated that the submitted invoice price was more representative of the commercial price than our CY 2019 research and pricing. We proposed the new invoice prices for these supply and equipment items due to our belief in their greater accuracy.

For some of the remaining supply and equipment items, such as the five-gallon paraffin (EP031) equipment and the Olympus DP21 camera (EP089) equipment, we maintained the extant pricing for CY 2019 due to a lack of sufficient data to update the pricing. In these situations where we did not have an updated price for CY 2019, we believe that the newly submitted invoices are more representative of the current commercial prices that are being paid on the market. We proposed the new invoice prices for these supply and equipment items due to our belief in their greater accuracy.

In addition, we were alerted by stakeholders that the price of the EM visit pack (SA047) supply did not match the sum of the component prices of the supplies included in the pack. After reviewing the prices of the individual component supplies, we agree with the stakeholders that there was a discrepancy in the previous pricing of this supply pack. We proposed to update the price of the EM visit pack to $5.47 to match the sum of the prices of the component supplies, and proposed to continue to transition towards this price over the remaining years of the phase-in period.

We finalized a policy last year to phase in the new supply and equipment pricing over 4 years so that supply and equipment values transition smoothly from their current prices to the final updated prices in CY 2022. We finalized our proposal to implement this pricing transition such that one quarter of the difference between the current price and the fully phased in price was implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 11. For CY 2020, one third of the difference between the CY 2019 price and the final price will be implemented as per the previously finalized policy. Table 12 contains the list of proposed CY 2020 market-based supply and equipment pricing updates:

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TABLE 12: Proposed CY 2020 Market-Based Supply and Equipment Pricing Updates

CMS CODE	Description	CMS 2019 Price	Prior CMS 2022 Price	Prior CMS 2020 Price	Updated CMS 2022 Price	Updated CMS 2020 Price
SA047	pack, EM visit	$4.176	$7.750	$5.367	$5.468	$4.606
SA099	Kit, probe, cryoablation, prostate (Galil-Endocare)	$3,909.890	$1,539.560	$3,119.780	$4,000.000	$3,939.927
SA106	kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)	$2,543.478	$2,374.330	$2,487.095	$2,338.000	$2,474.985
SD005	biopsy sponge (Histo-Prep)	$0.048	$0.030	$0.042	$0.267	$0.121
SF030	laser tip, diffuser fiber	$699.375	$247.500	$548.750	$730.000	$709.583
SH056	phenylephrine 2.5% ophth (Mydfrin)	$0.391	$0.391	$0.391	$5.465	$2.082
SH058	proparacaine 0.5% ophth (Ophthaine, Alcaine)	$0.615	$0.670	$0.633	$2.353	$1.194
SH084	Kenalog 40 inj	$1.963	$2.360	$2.095	$10.578	$4.834
SJ041	povidone soln (Betadine)	$0.016	$0.040	$0.024	$0.380	$0.137
SL012	antibody IgA FITC	$38.391	$30.025	$35.603	$87.500	$54.761
SL058	embedding cassette	$0.149	$0.120	$0.140	$0.181	$0.160
SL182	mounting media (DAPI II counterstain)	$63.750	$54.000	$60.500	$95.280	$74.260
SL184	slide, negative control, Her-2	$29.400	$29.400	$29.400	$27.500	$28.767
SL195	kit, FISH paraffin pretreatment	$20.850	$20.850	$20.850	$22.000	$21.233
SL196	kit, HER-2/neu DNA Probe	$98.513	$79.050	$92.025	$119.740	$105.588
SL484	Bluing reagent (Ventana 760-2037)	$3.504	$0.450	$2.486	$4.247	$3.751
SL497	(EBER) DNA Probe Cocktail	$8.475	$8.189	$8.379	$10.810	$9.253
EL015	room, ultrasound, general	$369,945.000	$369,945.000	$369,945.000	$410,303.322	$383,397.774
EL016	room, ultrasound, vascular	$466,492.000	$466,492.000	$466,492.000	$479,753.320	$470,912.440
EP001	DNA/digital image analyzer	$193,749.959	$28,160.937	$138,553.619	$225,143.420	$204,214.446
EP007	centrifuge (with rotor)	$4,442.759	$4,896.085	$4,593.868	$4,896.085	$4,593.868
EP015	grossing station w-heavy duty disposal	$21,200.775	$24,276.600	$22,226.050	$25,734.940	$22,712.163
EP017	hood, fume	$4,769.200	$4,741.420	$4,759.940	$5,978.210	$5,172.203
EP024	microscope, compound	$10,066.336	$5,401.295	$8,511.323	$9,764.720	$9,965.798
EP026	microscope, electron, transmission (TEM)	$350,736.063	$445,074.250	$382,182.125	$486,912.125	$396,128.083

CMS CODE	Description	CMS 2019 Price	Prior CMS 2022 Price	Prior CMS 2020 Price	Updated CMS 2022 Price	Updated CMS 2020 Price
EP031	paraffin dispenser (five-gallon)	$2,222.500	$2,222.500	$2,222.500	$2,500.000	$2,315.000
EP033	slide coverslipper, robotic	$30,143.000	$30,143.000	$30,143.000	$52,970.000	$37,752.000
EP036	slide stainer, automated, high-volume throughput	$19,334.532	$35,081.087	$24,583.384	$37,012.544	$25,227.202
EP039	tissue embedding center	$9,612.753	$11,161.000	$10,128.835	$12,560.500	$10,595.335
EP043	water bath, general purpose (lab)	$757.256	$849.673	$788.062	$950.337	$821.616
EP054	water bath, FISH procedures (lab)	$1,977.253	$1,576.010	$1,843.505	$1,576.100	$1,843.535
EP088	ThermoBrite	$5,788.750	$4,795.000	$5,457.500	$4,625.073	$5,400.858
EP089	Camera (Olympus DP21)	$7,719.300	$7,719.300	$7,719.300	$8,715.000	$8,051.200
EP111	Automated Casette Labeler	$9,541.385	$26,579.539	$15,220.770	$26,700.265	$15,261.011
ER041	microtome	$14,087.605	$16,243.420	$14,806.210	$17,709.840	$15,295.017
ER043	microtome, ultra	$33,628.850	$31,378.400	$32,878.700	$35,015.480	$34,091.060

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(2) Invoice Submission

The full list of updated supply and equipment pricing as it will be implemented over the 4-year transition period will be made available as a public use file displayed on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We received public comments on updates to prices for existing direct PE inputs. The following is a summary of the comments we received and our responses.

Comment: Many commenters were supportive of the proposed update to supply and equipment pricing based on the submission of additional invoices as detailed in Table 12. One commenter thanked CMS for gathering additional pertinent information and proposing a more accurate price for the balloon sinus surgery kit (SA106) supply for CY 2020. Several commenters urged CMS to finalize the proposed updates to the direct PE supplies and equipment prices as listed in the table. One commenter encouraged CMS to continue to carefully consider all pricing data including invoices and other supporting evidence that they receive from the specialty societies throughout this comment period and the entirety of the 4-year transition period.

Response: We will continue to carefully consider all pricing data submitted from commenters throughout the 4-year transition period.

Comment: Several commenters stated that they were concerned that supply and equipment pricing will quickly become outdated once the transition to updated prices is complete in CY 2022. The commenters encouraged CMS to move to an ongoing update process for supplies and equipment, as well as for clinical labor staff costs, one that is open for public comment through the rulemaking process.

Response: We share the concerns from the commenters that the supply and equipment pricing will eventually become outdated again after the pricing transition is complete. We welcome additional feedback from stakeholders on potential solutions to this issue, and we will consider the possibility of different approaches to supply and equipment pricing for use in future rulemaking.

Comment: One commenter stated that they appreciated and supported recognition by CMS that the supplies and equipment associated with physician services were past due for review, but noted that there remains large numbers of supplies and equipment that are overdue for updates. The commenter stated that they supported a gradual transition of the pricing given the widespread impact on the PE values; however, doing so creates a situation in which items that have seen dramatic increases over a short time are not being adequately compensated for several years. The commenter asked CMS to consider shortening the transition period from 4 years to 3 years for the supply and equipment pricing.

Response: Although we appreciate the feedback from the commenter, we finalized a policy last year to phase in the new supply and equipment pricing over 4 years so that supply and equipment values transition smoothly from their current prices to the final updated prices in CY 2022 (83 FR 59479–59480). We did not propose any changes to this transition period, and therefore, we decline to adopt a different approach.

Comment: One commenter stated that they supported the CMS proposal to update the price of the EM visit pack (SA047) supply to $5.47 to match the sum of the prices of the component supplies. The commenter also stated that they had concerns over the pricing of the other bundled supply items (such as kits, trays, and packs) that may have been similarly mispriced by StrategyGen. The commenter stated that they could not assist CMS in correcting supply codes that may have been incorrectly priced without details about the pricing for individual component supplies.

Response: We appreciate the support for our proposed pricing of the EM visit pack (SA047) supply by the commenter. We encourage stakeholders to comment

upon and submit pricing information for any supply items that they believe may have been mispriced by StrategyGen. In the absence of alternative pricing information, we continue to believe that our proposed prices are the most accurate source of data.

Comment: One commenter recommended CMS consider only the best available evidence and market research data in proposing any changes to the pricing approach of the balloon sinus surgery kit (SA106). The commenter stated that the use of navigation instruments has increased for this supply kit, particularly in the lower cost office setting, which enhances the ability to navigate the complex sinus anatomy, resulting in improved safety and reliability of the procedure, which benefits the patient.

Response: We note that the commenter did not make any specific recommendations regarding the pricing of this supply or submit invoices with additional pricing information. In the absence of alternative pricing information, we continue to believe that our proposed prices are the most accurate source of data.

Comment: Several commenters stated that they supported and urged CMS to finalize the proposed prices for the general ultrasound room (EL015) and vascular ultrasound room (EL016) equipment. Commenters stated that the proposed prices more accurately reflected the costs faced by vascular ultrasound practitioners and would reduce health care costs by ensuring ultrasound services are readily available to the most vulnerable Medicare beneficiaries.

Response: We appreciate the support for our proposed pricing by the commenters.

Comment: One commenter disagreed with the proposed pricing of the general ultrasound room (EL015) equipment. The commenter stated that the proposed pricing would drastically reduce the general ultrasound room price by 65 percent, which would have a downstream impact on the vascular ultrasound room, resulting in a 57 percent reduction. The commenter stated that a 40 percent reduction in payment as a result of this pricing would significantly reduce patient access to ultrasound services across the board.

Response: We clarify for the commenter that we did not propose a reduction in the price of the general ultrasound room (EL015) equipment. We proposed to update the price of the general ultrasound room to $410,303.32 and proposed to continue to transition towards this price over the remaining years of the phase-in period, with a CY 2020 price of $383,397.77. We note that this is a slight increase over the finalized CY 2019 price of $369,945.00; we encourage readers to consult the full list of supply and equipment pricing as detailed in the public use files.

Comment: Several commenters disagreed with the proposed pricing of the ''HDR Afterload System, Nucletron—Oldelft'' (ER003) equipment, the ''treatment planning system, IMRT (Corvus w-Peregrine 3D Monte Carlo)'' (ED033) equipment, and the ''SRS system, SBRT, six systems, average'' (ER083) equipment. The commenters stated that all of these equipment items have proposed prices that are below industry standards, and that given the high cost of these items and their substantial utilization in certain radiation oncology delivery codes, it was imperative that the CMS inputs accurately reflect the marketplace pricing. The commenters recommended that CMS conduct additional research regarding fair and accurate market pricing for equipment items ER003, ED033 and ER083. Another commenter also disagreed with the proposed pricing of the ER003 equipment, and stated that StrategyGen may have included updated pricing for a less costly electronic brachytherapy system used to treat non-melanoma skin cancer, or alternatively the proposed price for ER003 may represent an equipment upgrade or refurbished equipment.

Response: We share the concerns of the commenters on the importance to ensure fair and accurate market-based pricing for supplies and equipment. However, the commenters did not submit invoices or other pricing data for the ER003, ED033, and ER083 equipment items, and, as previously stated, in the absence of alternative pricing information, we continue to believe that our proposed prices are the most accurate source of data. We continue to welcome feedback from stakeholders on the proposed updated supply and equipment pricing over the ongoing 4-year transition period, including the submission of additional invoices for consideration.

Comment: Several commenters stated that they supported the efforts by CMS to ensure accurate pricing for direct PE inputs and supported the updated valuation of the ultrasound room and vascular ultrasound room. However, the commenters stated that there was an inconsistency with the pricing for the CT room (EL007), PET room (EL009), and PET–CT room (EL010) equipment. The commenters stated that it did not follow logically that the EL009 equipment is increasing from $1,328,996 to $2,410,677 and the EL007 equipment is increasing from $1,284,000 to $1,429,967 while a room that is a combination of these two, EL010, is decreasing from $2,136,283 to $206,326. The commenters asked that CMS investigate this issue further while delaying any price change for this one item.

Response: With regards to the pricing of the PET–CT room (EL010) equipment, we share the desire of the commenters to ensure fair and accurate market-based pricing for this equipment item. However, as we noted in the previous comment response, the commenters did not submit invoices or other pricing data for the EL010 equipment, and, as previously stated, in the absence of alternative pricing information, we continue to believe that our proposed prices are the most accurate source of data. We remind stakeholders that the proposed pricing was based on market research carried out by the StrategyGen contractor during the prior rule cycle. We continue to welcome feedback from stakeholders on the proposed updated supply and equipment pricing over the ongoing 4-year transition period, and we are willing to revisit the subject of pricing for this equipment if provided with market-based pricing data.

Comment: Several commenters disagreed with the proposed price of the ''stent, vascular, deployment system, Cordis SMART'' (SA103) and ''stent, balloon, implantable'' (SD299) supplies. Commenters stated that the Cordis SMART stent (SA103) supply is not FDA approved to stent iliac veins in CPT codes 37238–37239 due to the markedly undersized diameters of the available stents, and that this supply is essentially never used in iliac veins due to its much smaller size. The commenter stated that they believe the proposed pricing of the SA103 supply to be inaccurate, and stated that they were submitting 10 invoices in the hopes of pricing a new supply code at $2,537 which would replace the SA103 supply in these CPT codes. The commenters also stated a desire to work with CMS to reconsider pricing of the SD299 supply given the likely non-viability by CY 2022 of the services represented by CPT codes 37236 and 37237 in the office setting, and to resolve the lack of clarity surrounding the implantable stent balloon.

Response: We appreciate the desire on the part of the commenters to submit invoices with additional pricing data. However, despite an exhaustive search of the comments, we were unable to find the 10 invoices mentioned in the letters from the commenters, which

were not included along with the rest of the submitted text. Although we are willing to consider these invoices if they were to be submitted, as previously stated, in the absence of alternative pricing information, we continue to believe that our proposed prices are the most accurate source of data. We urge commenters submitting invoices to include them as part of their comment letter to avoid any potential for miscommunication. We also note for the commenters that we did not make any proposals regarding CPT codes 37238–37239 or CPT codes 37236–37237, and therefore, we decline to make changes to the supplies for these codes at this time.

Comment: Several commenters disagreed with the proposed price of the percutaneous neuro test stimulation kit (SA022) supply. The commenters stated that the proposed price of $114.52 was insufficient to reflect the cost associated with the SA022 supply, and that there may have been some misunderstanding about what items comprise the sacral nerve test kit. The commenters stated that it appears that the line item reflecting the device that generates the neurostimulation, which is the most expensive component of the test kit, was not included in the proposed pricing for this supply, which instead reflects the costs of the test kit leads only. The commenters stated that they reviewed all of the paid invoices for kits sold during January and February 2019, which resulted in pricing that was more in line with the CY 2018 pricing of $420 for the kit. One commenter submitted a random sample of 120 paid invoices (out of the 481 paid invoices that the commenter accumulated in total) for consideration by CMS.

Response: We appreciate the submission of a large quantity of additional invoices with pricing data from the commenter. After further review, we agree with the commenters that the proposed price failed to incorporate all of the components of the test kit. Based on the data submitted by the commenters, we are finalizing an update in the price of the percutaneous neuro test stimulation kit (SA022) supply to $413.24, and we will continue to transition towards this price over the remaining years of the phase-in period.

Comment: One commenter stated that the proposed price of $752.40 for the ''plasma LDL adsorption column (Liposorber)'' (SD186) supply did not accurately reflect the actual average prices paid by their provider customers. The commenter submitted copies of all U.S. customer invoices for purchases of the SD186 supply for the most recent three-month period from June 1 through August 30, 2019 and requested that the price should be updated to reflect the average market pricing.

Response: We appreciate the submission of a large quantity of additional invoices with pricing data from the commenter. Based on the data submitted by the commenter, we are finalizing an update in the price of the ''plasma LDL adsorption column (Liposorber)'' (SD186) supply to $1118.06, and we will continue to transition towards this price over the remaining years of the phase-in period.

Comment: The same commenter stated that the ''plasma antibody adsorption column (Prosorba)'' (SD185) supply was withdrawn from the market by its manufacturer more than 10 years ago, and the associated procedure code (CPT code 36515) has been deleted. The commenter also stated that the blood warmer tubing set (SC084) supply is not utilized to perform LDL apheresis with a Liposorber System, and therefore, recommended that this supply should be delisted as a direct PE input for CPT code 36516.

Response: We appreciate the additional information provided by the commenter regarding these supply items. After conducting our own review, we agree with the commenter that there is no longer any need for the ''plasma antibody adsorption column (Prosorba)'' (SD185) supply, which is not utilized by any HCPCS codes and has been withdrawn from the market. Therefore, we are finalizing the deletion of the SD185 supply code. We are not finalizing the removal of the blood warmer tubing set (SC084) supply at this time, as it is currently utilized in two codes (CPT codes 36514 and 36516), and we did not make any proposals on this issue. We welcome additional feedback from stakeholders regarding the use of the SC084 supply for potential future rulemaking.

Comment: One commenter stated that they appreciated recent efforts by CMS to update the price of supply and equipment inputs to better reflect current market rates. The commenter requested that CMS update the price inputs for three inputs: The Biodegradable Material Kit—PeriProstatic (SA126) supply, the Rezum delivery device kit (SA128) supply, and the water thermotherapy procedure generator (EQ389) equipment. The commenter submitted invoices with updated pricing data for consideration by CMS.

Response: Based on the data submitted by the commenters, we are finalizing an update in the price of all three of these direct PE inputs. We are finalizing an increase in the price of the Biodegradable Material Kit—PeriProstatic (SA126) supply from $2,850 to $2,965 based on averaging the submission of eight invoices. We are finalizing an increase in the price of the Rezum delivery device kit (SA128) supply from $1,150 to $1,220 based on averaging the submission of ten invoices. Finally, we are finalizing an increase in the price of the water thermotherapy procedure generator (EQ389) equipment from $27,538 to $33,950 based on averaging the submission of two invoices.

Comment: One commenter disagreed with the proposed pricing for the ''fluorescein inj (5ml uou)'' (SH033) supply. The commenter stated that the proposed price for injectable fluorescein was concerning as it did not reflect the most recent price increase of nearly 60 percent. The commenter stated that for several months practices have been paying $38.02 per vial and submitted four invoices to this effect.

Response: After reviewing the submitted invoices, we are finalizing an increase of the price of the SH033 supply to $38.02 to match the information detailed by the commenter.

Comment: One commenter disagreed with the proposed pricing for HCPCS code G0166 (*External counterpulsation, per treatment session*) and stated that the reductions in the proposed pricing would decrease the availability of this service and have already impacted their ability to provide external counterpulsation (ECP) therapy. The commenter stated that the prior review of HCPCS code G0166 in the CY 2019 rule cycle contained major errors, including omissions that artificially deflated the cost of the equipment associated with ECP therapy, inappropriate valuation of the ECP therapy equipment, and a failure to reflect the clinical guidelines and requirements for delivering ECP therapy. The commenter requested that CMS reverse the CY 2019 RVU reductions such that ECP therapy would return to the CY 2018 payment rates, or alternately pause any future reductions until CMS considered and acted upon forthcoming RUC recommendations for HCPCS code G0166. The commenter also submitted a series of invoices for the EECP external counterpulsation system (EQ012) equipment and a number of additional equipment items that previously lacked pricing.

Response: We remind commenters that we nominated HCPCS code G0166 as potentially misvalued in the CY 2020 PFS proposed rule (84 FR 40516) due to concerns that the RVUs for this code did not fully reflect the total resources required to deliver the service. Aside from nominating HCPCS code G0166 as

potentially misvalued, we did not make any other proposals concerning this code. We are aware that the RUC plans to review HCPCS code G0166 for the CY 2021 PFS rule cycle, and we look forward to considering their recommendations for next year's rulemaking.

However, although we are not reviewing the work RVU or direct PE inputs for HCPCS code G0166 for CY 2020, we were able to consider the submission of invoices from the commenter as part of our market-based supply and equipment pricing transition. Based on the information provided by the commenters, we are finalizing an increase in the price of the EECP external counterpulsation system (EQ012) equipment from $61,490.75 to $117,495.00. For the additional equipment items submitted by the commenter, which are not currently included in the direct PE inputs for HCPCS code G0166, we are finalizing the use of a proxy item for equipment pricing. We are finalizing the addition of a medium instrument pack (EQ138) priced at $1,500.00 at the same equipment time of 73 minutes used by the EECP external counterpulsation system as a proxy to represent the cost of these additional items. Although the medium instrument pack is a collection of surgical instruments and not table accessories, it contains 20 different small items which individually fall under our $500 threshold for equipment pricing, much as the additional equipment items on the submitted invoices also failed to meet the typical $500 threshold. We will further consider pricing for both the EECP external counterpulsation as part of the review process for this code along with the RUC recommendations when they arrive for CY 2021.

Comment: One commenter disagreed with the proposed pricing of the INR analysis and reporting system w-software (EQ312) equipment. The commenter stated that the finalized price for the INR analysis and reporting system during the CY 2019 rule cycle was orders of magnitude lower than the amount submitted by the home INR manufacturers and suppliers, and the commenter was under the belief that the pricing for this equipment was not reviewed and/or updated. The commenter urged CMS to review and update the price for the PT/INR analysis and reporting system based on current market invoices; the commenter also submitted additional invoices from the same vendor with their letter.

Response: We clarify for the commenter that we did review the invoices that they submitted during the previous rule cycle in CY 2019. Those invoices, along with the additional invoices submitted for the current CY 2020 rule cycle from the same vendor, did not contain pricing information for the purchase of an INR analysis and reporting system (EQ312) equipment item. These invoices instead constituted a monthly service fee for ''customization and management of provided applications'' as detailed on the billing form. Under our PE methodology, monthly service fees are a form of administrative expense, and payment for these costs is included as part of our indirect PE allocation. We did not use these invoices for pricing in CY 2019 and we are not using them for pricing in CY 2020, as they detail a form of indirect PE under our methodology. We also note that the equipment per-minute cost formula includes maintenance costs, interest costs, and a useful life assumption; this formula already incorporates equipment costs that extend across multiple years. Taking a monthly service fee and multiplying it across 12 months and then again across 5 years, as the commenters suggested should take place for these invoices, would result in equipment costs that are inappropriately excessive, such as the $6 million equipment price detailed on these invoices. We will continue to price the INR analysis and reporting system at $19,325 and continue to transition towards this price over the remaining years of the phase-in period.

After consideration of the public comments, we are finalizing the market-based supply and equipment pricing updates listed in Table 12, along with the additional finalized pricing changes detailed in the preceding paragraphs. The full list of updated supply and equipment pricing as it will be implemented over the 4-year transition period will be made available as a public use file displayed on the CMS website under downloads for the CY 2020 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. For CY 2020, we noted that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes after the February 10th deadline established for code valuation recommendations. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we would consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

(3) Adjustment to Allocation of Indirect PE for Some Office-Based Services

In the CY 2018 PFS final rule (82 FR 52999 through 53000), we established criteria for identifying the services most affected by the indirect PE allocation anomaly that does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. We also finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services. The methodology, as described, is based on the difference between the ratio of indirect PE to work RVUs for each of the codes meeting eligibility criteria and the ratio of indirect PE to work RVU for the most commonly reported visit code. We refer readers to the CY 2018 PFS final rule (82 FR 52999 through 53000) for a discussion of our process for selecting services subject to the revised methodology, as well as a description of the methodology, which we began implementing for CY 2018 as the first year of a 4-year transition. For CY 2020, we proposed to continue with the third year of the transition of this adjustment to the standard process for allocating indirect PE.

We did not receive any public comments on the proposed adjustments to allocation of indirect PE for some office-based services. Therefore, we are finalizing the continuation of the third year of the transition as proposed.

e. Technical Evaluation Panel Related to Practice Expense

The RAND Corporation is currently studying potential improvements to CMS' PE allocation methodology and the data that underlie it. As part of this study, RAND will be convening a technical expert panel in late 2019 or early 2020 to obtain input from stakeholders including physicians, practice and health system managers, health care accountants, and health policy experts. The expert panel's recommendations will be discussed in a

report to be published by RAND in CY 2020.

C. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: Work, PE, and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period (79 FR 67591 through 67596), we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs, *see* the CY 2015 PFS proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596). In the CY 2018 PFS proposed rule (82 FR 33965 through 33970), we proposed to update the specialty-level risk factors, used in the calculation of MP RVUs, prior to the next required 5 year update (CY 2020), using the updated MP premium data that were used in the eighth Geographic Practice Cost Index (GPCI) update for CY 2017; however the proposal was ultimately not finalized for CY 2018.

We consider the following factors when we determine MP RVUs for individual PFS services: (1) Specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners; (2) service-level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service-level risk factor based on either the higher of the work RVU or clinical labor portion of the direct PE RVU. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjusted (or scaled) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code was 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach, the same risk factor (RF) was applied for the new/revised code and source code, but the work RVU for the new/revised code was used to adjust the MP RVUs for risk.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk for intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the three most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty-level risk factor to individual codes based on the same utilization assumptions we make regarding specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-level risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

Section 1848(e)(1)(C) of the Act requires us to review, and if necessary, adjust the GPCIs at least every 3 years. For CY 2020, we are conducting the statutorily required 3-year review of the GPCIs, which coincides with the statutorily required 5-year review of the MP RVUs. We note that the MP premium data used to update the MP GPCIs are the same data used to determine the specialty-level risk factors, which are used in the calculation of MP RVUs. Going forward, we believe it would be logical and efficient to align the update of MP premium data used to determine the MP RVUs with the update of the MP GPCIs. Therefore, we proposed to align the update of MP premium data with the update to the MP GPCIs, that is, we proposed to review, and if necessary update the MP RVUs at least every 3 years, similar to our review and update of the GPCIs. If we align the two updates, we would conduct the next statutorily-mandated review and update of both the GPCI and MP RVU for implementation in CY 2023. We proposed to implement the fourth comprehensive review and update of MP RVUs for CY 2020 and are seeking comment on these proposals.

We received no specific comment regarding our proposal to align the update of MP premium data with the update to the MP GPCIs. That is, to review, and if necessary update the MP RVUs at least every 3 years, similar to our review and update of the GPCIs; therefore, we are finalizing as proposed.

2. Methodology for the Proposed Revision of Resource-Based Malpractice (MP) RVUs

a. General Discussion

We calculated the proposed MP RVUs using updated MP premium data obtained from state insurance rate filings. The methodology used in calculating the proposed CY 2020 review and update of resource-based MP RVUs largely parallels the process used in the CY 2015 update; however, we proposed to incorporate several methodological refinements, which are described below. The MP RVU calculation requires us to obtain information on specialty-specific MP premiums that are linked to specific services, and using this information, we derive relative risk factors (RFs) for the various specialties that furnish a particular service. Because MP premiums vary by state and specialty, the MP premium information must be weighted geographically and by specialty. We calculated the proposed MP RVUs using four data sources: MP premium data presumed to be in effect as of December 31, 2017; CY 2018 Medicare payment and utilization data; higher of the CY 2020 proposed work RVUs or the clinical labor portion of the direct PE RVUs); and CY 2019 GPCIs. We used the higher of the CY 2020 final work RVUs or clinical labor portion of the direct PE RVUs in our calculation to develop the CY 2020 final MP RVUs while maintaining overall PFS budget neutrality.

Similar to the CY 2015 update, the proposed MP RVUs were calculated using specialty-specific MP premium data because they represent the expense incurred by practitioners to obtain MP insurance as reported by insurers. For CY 2020, the most current MP premium data available, with a presumed effective date of no later than December 31, 2017, were obtained from insurers with the largest market share in each

state. We identified insurers with the largest market share using the National Association of Insurance Commissioners (NAIC) market share report. This annual report provides state-level market share for entities that provide premium liability insurance (PLI) in a state. Premium data were downloaded from the System for Electronic Rates & Forms Filing Access Interface (SERFF) (accessed from the NAIC website) for participating states. For non-SERFF states, data were downloaded from the state-specific website (if available online) or obtained directly from the state's alternate access to filings. For SERFF states and non-SERFF states with online access to filings, the 2017 market share report was used to select companies. For non-SERFF states without online access to filings, the 2016 market share report was used to identify companies. These were the most current data available during the data collection and acquisition process.

MP insurance premium data were collected from all 50 States, and the District of Columbia. Efforts were made to collect filings from Puerto Rico; however, no recent filings were submitted at the time of data collection, and therefore, filings from the previous update were used. Consistent with the CY 2015 update, no filings were collected for the other U.S. territories: American Samoa, Guam, Virgin Islands, or Northern Mariana Islands. MP premiums were collected for coverage limits of $1 million/$3 million, mature, claims-made policies (policies covering claims made, rather than those covering losses occurring, during the policy term). A $1 million/$3 million liability limit policy means that the most that would be paid on any claim is $1 million and the most that the policy would pay for claims over the timeframe of the policy is $3 million. Adjustments were made to the premium data to reflect mandatory surcharges for patient compensation funds (PCF, funds used to pay for any claim beyond the state's statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in states where participation in such funds is mandatory.

Premium data were included for all physician and nonphysician practitioner (NPP) specialties, and all risk classifications available in the collected rate filings. Although premium data were collected from all states, the District of Columbia, and previous filings for Puerto Rico were utilized, not all specialties had distinct premium data in the rate filings from all states. In previous updates, specialties for which premium data were not available for at least 35 states, and specialties for which there were not distinct risk groups (surgical, non-surgical, and surgical with obstetrics) among premium data in the rate filings, were crosswalked to a similar specialty, either conceptually or based on available premium data. This resulted in not using those premium data because the 35 state threshold was not met. In the CY 2020 PFS proposed rule, we noted that the proposed methodological improvements discussed below expands the specialties and amount of filings data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs.

b. Proposed Methodological Refinements

For the CY 2020 update, we proposed the following methodological improvements to the development of MP premium data:

(1) Downloading and using a broader set of filings from the largest market share insurers in each state, beyond those listed as ''physician'' and ''surgeon'' to obtain a more comprehensive data set.

We received public comments on the proposed methodological improvement to download and use a broader set of filings from the largest market share insurers in each state, beyond those listed as ''physician'' and ''surgeon'' to obtain a more comprehensive data. The following is a summary of the comments we received and our responses.

Comment: Commenters noted appreciation for CMS' efforts to improve the premium data collection process and the opportunity to provide comments on the new methodology. Commenters were supportive of our proposed methodological refinement to download and use a broader set of filings from the largest market share insurers in each state, beyond those listed as ''physician'' and ''surgeon'' to obtain a more comprehensive data set.

Response: We thank commenters for their feedback and support; we are finalizing as proposed.

(2) Combining minor surgery and major surgery premiums to create the surgery service risk group, which yields a more representative surgical risk factor. In the previous update, only premiums for major surgery were used in developing the surgical risk factor.

We received public comments on the proposed methodological improvement to combine minor surgery and major surgery premiums to create the surgery service risk group, which yields a more representative surgical risk factor. In the previous update, only premium data for major surgery were used in developing the surgical risk factor. The following is a summary of the comments we received and our responses.

Comment: Commenters stated they appreciated that CMS considered methods to calculate surgical risk factors, but noted concerns with the method CMS used to classify surgeries as either minor or major, stating it was arbitrary and inconsistent with other CMS policy. Commenters further noted that the definition of minor surgeries and major surgeries should be consistent and developed with a consensus methodology among physician specialties. Commenters recommended that CMS work with the physician community to more accurately define major and minor surgeries.

Response: We thank commenters for their appreciation of our work to calculate a more representative surgical risk factor. We note that we did not propose definitions for minor and major surgery and will continue to work with all interested stakeholders on our proposals.

Comment: Commenters were not supportive of our proposal to categorize services between HCPCS 59000 and HCPCS 59899 as OB services and services between HCPCS 10000 and HCPCS 69999 (excluding the OB services) as surgical, with a physician work value greater than 5.00 as ''major'' surgery, for the purpose of the analysis. Commenters noted that in doing so, CMS selected an arbitrary and misguided definition of ''minor'' surgery for any code between the HCPCS 10000 and HCPCS 69999 section of the CPT code book with a physician work value less than 5.00. Commenters noted that if CMS intends to collect data at the minor vs major level, the data must reflect the different risk factors for those specialties and specifically be applied to codes defined as minor vs major surgery, and not broadly applied to an entire specialty. Commenters noted that the proposal could lead to an unfair valuation for certain specialties and services. The commenter further noted that CMS should hold off on moving to differentiating between minor and major surgeries until CMS is able to work with the RUC and impacted specialties to establish such definitions.

Response: We reiterate that we did not propose to define minor surgery and major surgery. The proposal leveraged an existing policy (64 FR 59834), that categorized services within the surgical range of HCPCS codes (and the list of invasive cardiology services outside the surgical range) as surgical. Building upon that existing policy, we proposed a methodological improvement to

combine minor surgery and major surgery premiums when both were delineated in rate filings for a specialty and to set a threshold of a physician work RVU greater 5.00 to categorize surgical services as major surgery, (surgical services under 5.00 would be categorized as minor surgery) for the purpose of the analysis. The methodological improvement would have developed a more representative surgical risk factor by combining minor surgery and major surgery premiums. We further note that this would have produced more data to use in the analysis and enabled the analysis to reflect a more representative risk factor for specialties that could have been applied to the code level for services categorized as minor surgery or major surgery. We note that in previous updates only major surgery premium data were used (when both minor surgery and major surgery are delineated on the rate filings for a specialty) to develop the surgical risk factors, this was based on a physician work RVU threshold of greater than 5.0, but was based on rate filings that delineated major surgery for a specialty.

In consideration of concerns from commenters, we are not finalizing our proposed methodological refinement to combine major surgery and minor surgery premiums when both are delineated on the rate filings for a specialty nor are we finalizing our proposal to use a physician work RVU greater than 5.00 as a threshold to categorize surgical services as major surgery (or to categorize surgical services under 5.00 as minor surgery), for the purpose of the analysis. Instead we are finalizing to maintain the current methodology and only use major surgery premium data when both minor surgery and major surgery are delineated in the rate filings for a specialty (minor surgery premium data are discarded in those cases) and to use minor surgery premium data when only minor surgery premium data are delineated in the rate filings for a specialty—to develop surgical risk factors. However, we note that the objective of our proposal was to develop a more representative surgical risk factor by refining our current methodology to allow for the use of rate filings data that delineated minor and major surgery. Our work to establish methods to categorize surgical services as minor and major surgery is ongoing, we look forward to working with and receiving feedback from stakeholders for consideration in future rulemaking.

(3) Utilizing partial and total imputation to develop a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings, which sometimes use unique specialty names.

In instances where insurers report data for some (but not all) specialties that explicitly corresponded to a CMS specialty, where those data were missing, we proposed to use partial imputation based on available data to establish what the premiums would likely have been had that specialty been delineated in the filing. In instances where there were no data corresponding to a CMS specialty in the filing, we proposed to use total imputation to establish premiums.

For example, if a specialty of Sleep Medicine is listed on some insurers' rate filings, this rate will be matched to the CMS specialty Sleep Medicine (C0)—partial imputation. However, if the Sleep Medicine specialty is not listed on the insurer's rate filing, under our proposed methodology, the insurer's rate filing for General Practice would be matched to the CMS specialty of Sleep Medicine (C0)—total imputation. In this example, we believe (consistent with the longstanding mappings of the regulatory impact table included in all PFS **Federal Register** notices) that the rate for General Practice is likely to be consistent with the rate that a Sleep Medicine provider would be charged by that insurer, this principle for mapping is used for the appropriate type of imputation. We note the proposed methodological improvement would mean that instead of discarding specialty-specific information from some insurers' filings because other insurers lacked that same level of detail, we would instead impute the missing rates at the insurer/specialty level to utilize as much of the information from the filings as possible.

We solicited comment on these proposed methodological improvements. Additional technical details about our proposal are available in our interim report, ''Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' on our website. It is located under the supporting documents section for the CY 2020 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

We received public comments on the proposed methodological improvement to utilize partial and total imputation to develop a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings, which sometimes use unique specialty names. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with some of the proposed specialty mappings for partial and total imputation. Some of these commenters recommended that CMS use different mappings other than those that were proposed. A few commenters recommended that CMS publish impacts for all CMS specialties and not attempt to bundle or map specialties to what CMS believes are related specialties or professions.

Response: We note that the MP RVU calculation requires us to obtain information on specialty-specific MP premiums that are linked to specific services, and using this information, we derive relative risk factors for the various specialties that furnish a particular service. We reiterate that the proposed mappings for partial imputation parallel the longstanding mappings of the regulatory impact table included in all PFS **Federal Register** notices that group CMS specialties (present on Medicare claims) into clusters of related specialties (impact specialties) when CMS examines the potential impact of PFS payment policies on the distribution of payments by providers. This table is included in section VII. of this final rule, the Regulatory Impact Analysis.

Furthermore, the proposed mappings for total imputation (when a CMS specialty name is not listed on the insurer's rate filing) reflect the speciality-specifc relationship of the underlying principle to identify the premium that an individual in a specialty would have been charged. The proposed mappings for total imputation, specifically for NPP specialties, parallel the proposal to crosswalk NPP specialties for which we do not have sufficient comparable professional liability data, to the lowest physician specialty, which was found to be allergy/immunology.

We note that partial and total imputation are necessary to expand the specialty specific filings data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs. This improvement resulted in the development of a more comprehensive data set, when CMS specialty names were not distinctly identified in the insurer filings, which sometimes use unique specialty names; we are finalizing as proposed.

Comment: A commenter noted that they joined the RUC in urging CMS to collect premium data for specialties that are missing data or where data are not available, and in the meantime, to work

with the RUC to better identify appropriate crosswalks.

Response: We reiterate that we have, and will continue to work with the RUC and all interested stakeholders to improve the premium data collection. Moreover, we continue to make progress in this area as evidenced in the CY 2020 PFS proposed rule (84 FR 40506), where we determined that there were sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 15 specialties, there were 10 such specialties in the CY 2015 update.

Comment: Commenters recommended that CMS utilize any and all premium data available to determine accurate crosswalks for specialties that cannot be directly matched to one of CMS' specialty names.

Response: We reiterate that we use all of the premium data collected to match CMS specialties to the rate that a provider in the specialty would have been charged under each filing, even though PLI insurers use their own distinctive specialty names.

Comment: One commenter recommended that CMS map RFs for cardiac electrophysiology to the risk factor for cardiology (surgery) and cardiology (no surgery). The commenter noted that they did not understand the rationale that CMS applied to determine that the RF should be set at 1.89 and ask CMS to detail how it arrived at that recommended RF. One commenter noted that electrophysiology is a distinct specialty of cardiology, with eligibility for board certification in clinical cardiac electrophysiology through the American Board of Internal Medicine, as well as in cardiology. Several commenters noted that cardiac electrophysiology is a relatively small specialty that may not clearly show in premium data. These commenters further noted that it would not make sense for services like pacemaker implantation that includes placing transvenous wires inside the heart or catheter ablations to treat cardiac arrhythmias inside the heart to receive a non-surgical PLI risk factor. Several commenters noted that cardiac electrophysiology currently has a surgery and non-surgery risk factor.

Response: We reiterate that details on the data sources and the methodological approach used to develop RFs are detailed in the CY 2020 PFS proposed rule (84 FR 40504) and the interim report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare PFS. We also remind stakeholders that we are using updated premium data as reported in the SERFF for participating states and downloaded from the state-specific website for non-SERFF states or obtained directly from the state's alternate access to filings to develop RFs. We were able to collect more data, and use those data to develop specialty-specific RFs for specialties that were previously entirely mapped to a different specialty out of necessity, because we did not have sufficient data. Therefore, we create a specialty-specific RF based on the distinct data of each specialty, as reflected in the rate filings, when sufficient. Thus, the RFs may be considerably different from the previous update, as a result of utilizing the specialty's own data and not that of a crosswalk to another specialty as was the case for cardiac electrophysiology in the proposed rule. Using these data, as reflected in the filings, more accurately reflects premiums associated with the specialty.

We appreciate the additional information provided by the commenters as to why cardiac electrophysiology should remain mapped to the RF for cardiology (surgery) and cardiology (no surgery). Upon additional review of the additional information provided by commenters, we are not finalizing our proposal to map cardiac electrophysiology to a RF of 1.89, and instead we are finalizing the mapping of RFs for cardiac electrophysiology to the risk factor for cardiology (surgery) and cardiology (no surgery).

Comment: One commenter stated that while the proposal maintains CMS' established policy of applying the cardiology surgical risk factor to the procedures identified in Table 15 of the CY 2015 PFS proposed rule (79 FR 40353 through 40354), it is inconsistent with the CY 2015 PFS final rule, wherein CMS finalized that the cardiology surgical risk factor would apply to a list of procedures (classified as injection procedures used in conjunction with cardiac catheterization) that are outside the code range that CMS considered surgical. This same commenter stated they are concerned that the proposal to have fewer subgroups for cardiac electrophysiology inadvertently undervalues many cardiology surgical procedures on the basis of subspecialty mix performing the procedure, rather than valuing the procedure on its surgical status.

Response: We believe the commenter may have misinterpreted both the CY 2015 PFS proposed rule (79 FR 40353) and CY 2015 PFS final rule (79 FR 67595), which led to a subsequently misinterpreting what CMS proposed to maintain in the CY 2020 PFS proposed rule (84 FR 40504). In CY 2015, we finalized a policy to classify invasive cardiology services (cardiac catheterizations and angioplasties) that are outside of the surgical HCPCS code range as surgery for purposes of assigning specialty-specific risk factors, and to apply the higher cardiology surgical risk factor to the list of codes outside of the surgical HCPCS code range, when those services are performed by providers with a specialty of cardiology. To that end, this is not to imply that we apply the higher cardiology surgical risk factor to the cardiology services that are outside the surgical code range regardless of the provider specialty performing those services, as indicated by the commenter. We note that the higher surgical risk factor is applied to the list of codes outside of the surgical HCPCS code range only when performed by a provider with a specialty of cardiology.

We reiterate, we calculate service level risk factors based on the mix of specialties that furnish a given service as indicated by Medicare claims data. Medicare claims data reflect the service volume by Medicare primary specialty designations. For CY 2020, we continue to classify services that are outside of the surgical HCPCS code range as surgery for purposes of assigning specialty-specific risk factors, and when furnished by providers with cardiology as the Medicare primary specialty code on the Medicare claim, apply the higher cardiology surgical risk factor.

Comment: One commenter expressed concern with the statement that cardiac electrophysiology is not typically associated with the number and mix of surgical services of other surgical specialties. The commenter further noted that cardiac electrophysiology accounts for about 75 percent of the utilization, on average, across the cardiac ablation codes, with the specialty of cardiology accounting for most of the remainder.

Response: We note that the statement ''cardiac electrophysiology is not typically associated with the number and mix of surgical services of cardiologists'' was not made to imply that providers with a specialty of cardiac electrophysiology do not perform surgical procedures. We acknowledge that providers with the specialty of cardiac electrophysiology perform surgical procedures, as evidenced by our classification of codes outside of the surgical HCPCS code range as surgery for purposes of assigning specialty-specific risk factors, which are performed by providers with specialty of cardiac electrophysiology and other specialties.

Furthermore, in the case of the list of invasive cardiology services, classified as surgery for purposes of assigning service level risk factors, we note that the percentage of allowed services attributed to cardiology decreased for some of these service codes while the percentage of allowed services furnished by other specialties with risk factors lower than cardiology, such as cardiac physiology, increased.

Additionally, we received several general comments related to the proposed methodological refinements.

Comment: One commenter noted appreciation for CMS' attempt to improve the premium data collection process, stating that the Agency was successful in acquiring national premium data for 16 specialties that were formerly mapped entirely to another specialty, and that there is no longer a mention of the arbitrary 35 state threshold used in the previous update that triggered the CMS crosswalk methodology used to develop PLI RVUs for specialties for which there was not premium data for at least 35 states.

Response: We note that implementation of the methodological refinements noted above, no longer necessitated the 35 state threshold.

Comment: One commenter noted concerns about the percentage of market share premium data that was collected for Connecticut and Massachusetts, noting that only 30 percent of market share data were collected in that locality, even though Connecticut has relatively high PLI premiums, when compared to the rest of the country.

Response: As detailed in the ''Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare PFS'', which is available on the CMS website under the downloads section of the CY 2020 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html* medical professional liability insurance is issued at maximum coverage limits. Premiums were collected for coverage limits of $1 million per occurrence and $3 million aggregate. States with Patient Compensation Funds may have different coverage limits, which we accounted for, as noted in the aforementioned final report. Although data collection for a state may not have met the threshold of collecting filings until either cumulative market share met or exceeded 50 percent or filings had been collected for four groups or companies, it does not imply that premiums were collected for coverage limits below $1 million per occurrence and $3 million aggregate.

We note that the market share filings for Connecticut met the threshold, because we collected data for four groups. In the case of Massachusetts, this is a non-SERFF state, so we were limited to the amount of data provided by the state in response to our request to the state for these data; we have revised Table 7.A in the final report to easily identify non-SERFF states.

Additionally, in our review of the findings reported in Table 7.A in the final report, we recognized the need for additional clarification for two states. We clarify that data collection for New York State did not meet either threshold, because some of the filings collected were incomplete and unusable, leaving data for three groups, accounting for 32 percent remaining for the market share analysis. In the case of Rhode Island, we identified a typographical error in the chart, which has been fixed.

Comment: Several commenters noted concerns with the data displayed in Table 8.B Volume-weighted Distribution of 2017 Physician Work RVUs by Service Type by CMS Specialty the final report.

Response: We thank commenters for noting their concerns. These data display the share of total work RVUs by service risk group used when combining or splitting premiums across service risk groups as reported by specialties on rate filings to match the final set of specialty/service risk groups used in the analysis. The data displayed in that table are solely for the purposes of the analysis. In consideration of the comments we received, we have provided additional details on the calculations in the ''Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare PFS'', which is available on the CMS website under the downloads section of the CY 2020 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* Additionally, the table has been revised to reflect that we are not finalizing our proposed methodological refinement to combine minor and major surgery premiums when both are present in the filings for a specialty.

c. Steps for Calculating Malpractice RVUs

Calculation of the proposed MP RVUs conceptually follows the specialty-weighted approach used in the CY 2015 PFS final rule with comment period (79 FR 67591), along with the above proposed methodological improvements. The specialty-weighted approach bases the MP RVUs for a given service on a weighted average of the risk factors of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are reflected in the calculation of the MP RVUs. The steps for calculating the proposed MP RVUs are described below. We note that not all of the proposed methodological refinements are being finalized, and therefore, some of steps for calculating malpractice RVUs differ from the proposal.

Step (1): Compute a preliminary national average premium for each specialty.

Insurance rating area MP premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2013–2017 American Community Survey (ACS) 5-year estimates). This is in contrast to the method used for creating national average premiums for each specialty in the 2015 update; in that update, specialty premiums were weighted by the total RVU per county, rather than by the county share of the total U.S. population. We refer readers to the CY 2016 PFS final rule with comment period (80 FR 70909) for a discussion of why we have adopted a weighting method based on share of total U.S. population. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic variation so that the locality cost differences (as reflected by the 2019 GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

Step (2): Determine which premium service risk groups to use within each specialty.

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. These premium classes are designed to reflect differences in risk of professional liability and the cost of MP claims if they occur. To account for the presence of different classes in the MP premium data and the task of mapping these premiums to procedures, we calculated distinct risk factors for surgical, surgical with obstetrics, and nonsurgical procedures where applicable. However, the availability of data by surgery and non-surgery varied across specialties. Historically, no single approach accurately addressed the variability in premium class among specialties, and we previously employed several

methods for calculating average premiums by specialty. These methods are discussed below.

Developing Distinct Service Risk Groups: We determined that there were sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 15 specialties (there were 10 such specialties in the CY 2015 update). These specialties are listed in Table 13. Additionally, as described in the proposed methodological refinements, in some instances, we combined minor surgery and major surgery premiums to create a premium to develop the surgery service risk group, rather than discard minor surgery premium data as was done in the previous update. We note that we are not finalizing the proposed methodological change to combine minor surgery and major surgery premium data when both are delineated the rate filings for a specialty. For all other specialties (those that are not listed in Table 13) that typically do not distinguish premiums as described above, a single risk factor was calculated, and that specialty risk factor was applied to all services performed by those specialties.

This is consistent with prior practice; however, we have refined the nomenclature to more precisely describe that some specialties are delineated into service risk groups, as is the case for surgical, non-surgical, and surgical with obstetrics, and some specialties are not further delineated into service risk subgroups and are instead referred to as ''All''—meaning that all services performed by that specialty receive the same risk factor.

TABLE 13: Specialties Subdivided into Service Risk Groups

Service Risk Groups	Specialties
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), Urology (34), Geriatric Medicine (38), Nephrology (39), Endocrinology (46), Podiatry (48), Emergency Medicine (93)
Surgery/No Surgery/OB	General Practice (01), Family Practice (08), OB/GYN (16)

Step (3): Calculate a risk factor for each specialty.

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty-level risk factor. These risk factors are calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowest premiums for which we had sufficient and reliable data, which remains allergy and immunology (03). For specialties with rate filings that are indicative of sufficient surgical and non-surgical premium data, we recognized those service-risk groups (that is, surgical, and non-surgical) as risk groups of the specialty and we calculated both a surgical and non-surgical risk factor. Similarly, for specialties with rate filings that distinguished surgical premiums with obstetrics, we recognized that service-risk subgroup of the specialty and calculated a separate surgical with obstetrics risk factor.

(a) Technical Component (TC) Only Services

We note that for determining the risk factor for suppliers of TC-only services in the CY 2015 update, we updated the premium data for independent diagnostic testing facilities (IDTFs) that we used in the CY 2010 update. Those data were obtained from a survey conducted by the Radiology Business Management Association (RBMA) in 2009; we ultimately used those data to calculate an updated TC specialty risk factor. We applied the updated TC specialty risk factor to suppliers of TC-only services. In the CY 2015 PFS final rule with comment period (79 FR 67595), RBMA voluntarily submitted updated MP premium information collected from IDTFs in 2014, and requested that we use those data to calculate the CY 2015 MP RVUs for TC-only services. We declined to utilize those data and stated that we believe further study is necessary and we would consider this matter and propose any changes through future rulemaking. We continue to believe that data for a broader set of TC-only services are needed, and are working to acquire a broader set of data.

For CY 2020, we proposed to assign a risk factor of 1.00 for TC-only services, which corresponds to the lowest physician specialty-level risk factor. We assigned the risk factor of 1.00 to the TC-only services because we do not have sufficient comparable professional liability premium data for the full range of clinicians that furnish TC-only services. In lieu of comprehensive, comparable data, we propose to assign 1.00, the lowest physician specialty-level risk factor calculated using the updated premium data, as the default minimum risk factor. However, we seek information on the most comparable and appropriate proxy for the broader set of TC-only services for future use, as well as any empirical information that would support assignment of an alternative risk factor for these services.

Table 14 shows the risk factors by specialty type and service risk group.

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TABLE 14: CY 2020 Risk Factors by Specialty and Service Risk Group

Medicare Specialty Code and Name	2020 Service Risk Group	2020 Risk Factor
01-General practice	NO SURG	1.63
01-General practice	SURG	3.48
01-General practice	OB	3.71
02-General surgery	ALL	6.88
03-Allergy/immunology	ALL	1.00
04-Otolaryngology	NO SURG	1.64
04-Otolaryngology	SURG	3.87
05-Anesthesiology	ALL	2.20
06-Cardiology	NO SURG	1.89
06-Cardiology	SURG	6.37
07-Dermatology	NO SURG	1.09
07-Dermatology	SURG	2.63
08-Family practice	NO SURG	1.63
08-Family practice	SURG	3.62
08-Family practice	OB	3.70
09-Interventional Pain Management	ALL	3.00
10-Gastroenterology	NO SURG	1.81
10-Gastroenterology	SURG	3.01
11-Internal medicine	ALL	1.78
12-Osteopathic manipulative therapy	ALL	1.00
13-Neurology	NO SURG	2.25
13-Neurology	SURG	10.43
14-Neurosurgery	ALL	10.43
15-Speech Language Pathology	ALL	1.00
16-Obstetrics/gynecology	NO SURG	1.86
16-Obstetrics/gynecology	SURG	4.45
16-Obstetrics/gynecology	OB	7.82
17-Hospice & Palliative Care	ALL	1.00
18-Ophthalmology	NO SURG	1.17
18-Ophthalmology	SURG	2.10
19-Oral surgery	ALL	2.41
20-Orthopedic surgery	ALL	5.61
21-Cardiac Electrophysiology	NO SURG	1.89
21-Cardiac Electrophysiology	SURG	6.37
22-Pathology	ALL	1.51
23-Sports Medicine	ALL*	1.67
24-Plastic and reconstructive surgery	ALL	4.98
25-Physical medicine and rehabilitation	ALL	1.38
26-Psychiatry	ALL	1.02
27-Geriatric Psychiatry	ALL	1.02
28-Colorectal surgery	ALL	3.59
29-Pulmonary disease	ALL	2.06
30-Diagnostic radiology	ALL	2.27
31-Intensive Cardiac Rehab	ALL	1.89
32-Anesthesiologist assistants	ALL	0.60
33-Thoracic surgery	ALL	6.45
34-Urology	NO SURG	1.67
34-Urology	SURG	3.24
35-Chiropractic	ALL	0.52

Medicare Specialty Code and Name	2020 Service Risk Group	2020 Risk Factor
36-Nuclear medicine	ALL	1.24
37-Pediatric medicine	ALL	1.82
38-Geriatric medicine	NO SURG	1.49
38-Geriatric medicine	SURG	3.56
39-Nephrology	NO SURG	1.67
39-Nephrology	SURG	2.91
40-Hand surgery	ALL	4.45
41-Optometry	ALL	0.17
42-Certified nurse midwife	ALL*	2.06
43-CRNA	ALL	0.68
44-Infectious disease	ALL	2.11
45-Mammography screening center	ALL	1.00
46-Endocrinology	NO SURG	1.59
46-Endocrinology	SURG	3.27
47-Independent Diagnostic Testing Facility	ALL	1.00
48-Podiatry	NO SURG	1.27
48-Podiatry	SURG	2.18
62-Psychologist	ALL	1.00
63-Portable X-ray supplier	ALL	1.00
64-Audiologist	ALL	1.00
65-Physical therapist	ALL	1.00
66-Rheumatology	ALL	1.63
67-Occupational therapist	ALL	1.00
68-Clinical psychologist	ALL	1.00
69-Clinical laboratory	ALL	1.00
70-Multispecialty clinic or group practice	ALL	2.25
71-Registered Dietician/Nutrition Professional	ALL	1.00
72-Pain management	ALL	2.97
75-Slide Preparation Facilities	ALL	1.00
76-Peripheral vascular disease	ALL	6.80
77-Vascular surgery	ALL	6.80
78-Cardiac surgery	ALL	6.37
79-Addiction medicine	ALL	1.00
80-Licensed clinical social worker	ALL	1.00
81-Critical care (intensivists)	ALL	2.28
82-Hematology	ALL	1.79
83-Hematology/oncology	ALL	1.85
84-Preventive medicine	ALL	1.38
85-Maxillofacial surgery	ALL	2.62
86-Neuropsychiatry	ALL	1.02
90-Medical oncology	ALL	1.86
91-Surgical oncology	ALL	6.55
92-Radiation oncology	ALL	2.03
93-Emergency medicine	NO SURG	3.00
93-Emergency medicine	SURG	5.76
94-Interventional radiology	ALL	2.76
98-Gynecologist/oncologist	ALL	4.45
99-Unknown physician specialty	ALL*	2.25
C0-Sleep Medicine	ALL	1.61
C3-Interventional Cardiology	ALL	6.21
C6-Hospitalist	ALL	2.13
C7-Advanced Heart Failure & Transplant Cardiology	ALL	6.37

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We received public comments on the steps for calculating MP RVUs. The following is a summary of the comments we received and our responses.

Comment: Commenters disagreed with our proposal to assign a risk factor of 1.00, which is the risk factor of the lowest physician specialty, to TC-only services because of insufficient comparable professional liability premium data for the full range of health professionals that furnish TC-only services. The commenters recommended retaining the current RF for TC-only services until comprehensive data is acquired rather

than assigning the lowest physician specialty-level risk factor to these services. Commenters noted that we should continue to work with stakeholders to obtain these data.

Response: We reiterate that we have, and will continue to work in collaboration with all interested stakeholders to find sufficient comparable professional liability data for the full range of clinicians that furnish TC-only services. In general, we continue to make progress in acquiring premium data as evidenced by the fact that for the CY 2020 update we collected service-specific premium data for an increasing number of specialties, as compared to the CY 2015 update. We note that the current RF for TC-only services is 0.91. Although we were able to find some data for health professionals that furnish TC-only services, we were unable to find sufficient comparable professional liability premium data for the full range of health professionals that furnish TC-only services. We are finalizing our proposal to assign a RF of 1.00, which is the RF of the lowest physician specialty (allergy/immunology), to TC-only services.

Comment: Commenters noted that consistent with the previous update CMS continued to assign the RF of the lowest physician specialty to NPPs for which there were insufficient or no premium data. We received contrasting comments on this proposal. For instance, one commenter was supportive of our proposal to continue assigning the risk factor of the lowest physician specialty to NPPs for which CMS was unable to collect sufficient data. In contrast, a few commenters, including the RUC, stated that CMS should not crosswalk NPPs to the lowest physician specialty, which is allergy and immunology, and to continue to aggressively collect premium data on NPPs.

Response: Our efforts to improve the premium data collection for NPPs is ongoing. We have made progress in acquiring premium data as evidenced by the fact that for the CY 2020 update we collected service-specific premium data for an increasing number of specialties, as compared to the CY 2015 update, including some NPP specialties, for which we previously did not have data that were mapped entirely to another specialty. Although we were able to find data for several NPPs for which we previously did not have data, we were unable to find premium data for the full range of NPPs. Premium data collection for NPPs is ongoing and will continue ahead of the next MP RVU update. We are finalizing a policy to maintain the current assignment of a RF of 1.00 for NPP specialties, which corresponds to the lowest physician specialty RF, allergy and immunology.

Comment: One commenter stated that an alternate option to crosswalking NPPs to the lowest physician risk factor of allergy and immunology would be to assign them the RF of another NPP specialty for which CMS was able to obtain data, the commenter recommended optometry.

Response: We reiterate that our proposal was to maintain the crosswalk of NPPs for which we had insufficient or no premium data to the lowest physician specialty, not to crosswalk NPPs to the RF of a NPP for which we were able to collect data. At this time, because we were unable to find premium data for the full range of NPPs, we do not believe it is appropriate, as suggested by commenters, to assign all NPPs for which we had insufficient or no premium data to the RF of optometry, another NPP specialty for which we were able to find some data. We reiterate that CMS' efforts to improve the premium data collection for all NPP specialties is ongoing and will continue ahead of the next MP RVU update.

Comment: One commenter suggested that the Agency assign codes performed predominantly by the select NPPs a 0.00 PLI as their premiums are so inconsequential that even a 0.01 PLI overcompensate them for their minimal PLI premiums.

Response: We disagree that NPPs should be assigned a 0.00 PLI and moreover, we disagree that even a 0.01 PLI overcompensate them for their minimal PLI premiums. This incorrectly implies that there is zero risk for NPPs to provide medical services. We reiterate that although we were able to find data for several NPP specialties for which we previously did not have data, we were unable to find premium data for the full range of NPP specialties. Premium data collection for NPP specialties is ongoing and will continue ahead of the next update.

Comment: One commenter noted that they previously referenced an insurance carrier, Health Providers Service Organization (HPSO) (*www.hpso.com*), as a source of potential premium data for most NPPs. This same commenter provided PLI premium data for several NPPs for a single state from this source, which ranged from $153 to $1,008.

Response: We thank the commenter for their feedback and potential data source, as CMS continues efforts to collect premium data on the full range of NPP specialties ahead of the next MP RVU update.

Step (4): Calculate MP RVUs for each CPT/HCPCS code.

Resource-based MP RVUs were calculated for each CPT/HCPCS code that has work or PE RVUs. The first step was to identify the percentage of services furnished by each specialty for each respective CPT/HCPCS code. This percentage was then multiplied by each respective specialty's risk factor as calculated in Step 3. The products for all specialties for the CPT/HCPCS code were then added together, yielding a specialty-weighted service specific risk factor reflecting the weighted MP costs across all specialties furnishing that procedure. The service specific risk factor was multiplied by the greater of the work RVU or clinical labor portion of the direct PE RVU for that service, to reflect differences in the complexity and risk-of-service between services.

Low volume service codes: As we discussed above in this final rule, for low volume services code, we finalized the proposal in the CY 2018 PFS final rule (82 FR 53000 through 53006) to apply the list of expected specialties instead of the claims-based specialty mix for low volume services to address stakeholder concerns about the year to year variability in PE and MP RVUs for low volume services (which also includes no volume services); these are defined as codes that have 100 allowed services or fewer. These service-level overrides are used to determine the specialty for low volume procedures for both PE and MP.

In the CY 2018 PFS final rule (82 FR 53000 through 53006), we also finalized our proposal to eliminate general use of an MP-specific specialty-mix crosswalk for new and revised codes. However, we indicated that we would continue to consider, in conjunction with annual recommendations, specific recommendations regarding specialty mix assignments for new and revised codes, particularly in cases where coding changes are expected to result in differential reporting of services by specialty, or where the new or revised code is expected to be low-volume. Absent such information, the specialty mix assumption for a new or revised code would derive from the analytic crosswalk in the first year, followed by the introduction of actual claims data, which is consistent with our approach for developing PE RVUs.

For CY 2020, we solicited public comment on the list of expected specialties. We also noted that the list has been updated to include a column indicating if a service is identified as a low volume service for CY 2020, and therefore, whether or not the service-level override is being applied for CY

2020. The proposed list of codes and expected specialties is available on our website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We received public comments on the proposed updates to the expected specialty list for low volume services. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that CMS had indicated that the expected specialty list would be updated to include a column specifying if a service was identified as a low volume service for CY 2020, indicating if the service-level override was being applied for CY 2020. However, commenters noted that this additional column did not appear in the download version and asked for additional information.

Response: We thank the commenters for identifying this missing information and we apologize for the technical oversight that caused this information not to be displayed for the proposed rule. We are finalizing a policy to include this additional column in the public use files released with the final rule. Additional comments on the proposed updates to the expected specialty list have been addressed in section II.B. of this final rule.

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. Thus, the last step is to adjust for relativity by rescaling the proposed MP RVUs so that the total proposed resource based MP RVUs are equal to the total current resource based MP RVUs scaled by the ratio of the pools of the proposed and current MP and work RVUs. This scaling is necessary to maintain the work RVUs for individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs.

Specialties Excluded from Ratesetting Calculation: In section II.B. of this final rule, Determination of Practice Expense Relative Value Units, we discuss specialties that are excluded from ratesetting for the purposes of calculating PE RVUs. We proposed to treat those excluded specialties in a consistent manner for the purposes of calculating MP RVUs. We note that all specialties are included for purposes of calculating the final BN adjustment. The list of specialties excluded from the ratesetting calculation for the purpose of calculating the PE RVUs that we proposed to also exclude for the purpose of calculating MP RVUs is available in section II.B. of this final rule, Determination of Practice Expense Relative Value Units. The resource-based MP RVUs are shown in Addendum B, which is available on the CMS website under the downloads section of the CY 2020 PFS rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

Because a different share of the resources involved in furnishing PFS services is reflected in each of the three fee schedule components, implementation of the resource-based MP RVU update will have much smaller payment effects than implementing updates of resource-based work RVUs and resource-based PE RVUs. On average, work represents about 50.9 percent of payment for a service under the fee schedule, PE about 44.8 percent, and MP about 4.3 percent. Therefore, a 25 percent change in PE RVUs or work RVUs for a service would result in a change in payment of about 11 to 13 percent. In contrast, a corresponding 25 percent change in MP values for a service would yield a change in payment of only about 1 percent. Estimates of the effects on payment by specialty type is detailed in section VII. of this final rule, the Regulatory Impact Analysis.

We received no specific comments regarding our proposal to treat excluded specialties in a consistent manner for the purposes of calculating MP RVUs, we are finalizing as proposed.

Additional information on our methodology for updating the MP RVUs is available in the ''Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' which is available on the CMS website under the downloads section of the CY 2020 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

After consideration of the comments, we are finalizing the CY 2020 update as proposed with minor modifications, as indicated above. We are finalizing our proposal to download and use a broader set of filings from the largest market share insurers in each state, beyond those listed as ''physician'' and ''surgeon'' to obtain a more comprehensive data set. We are not finalizing our proposal to combine minor and major surgery premiums when both are delineated on rate filings for a specialty nor are we finalizing our proposal to use a physician work RVU of greater than 5.00, as a threshold to identify surgical services as major surgery (or to categorize surgical services under 5.00 as minor surgery). Instead, we are finalizing a policy to develop RFs by maintaining the current methodology to only use major surgery premium data when both minor surgery and major surgery are delineated on rate filings for a specialty, and to use the minor surgery premium data when it is the only premium type in the rate filings for a specialty. We are finalizing a policy to map risk factors for cardiac electrophysiology to the risk factor for cardiology (surgery) and cardiology (no surgery). We are finalizing our proposal to assign the RF of the lowest physician specialty (allergy/immunology) to TC-only services, which is a RF of 1.00. We are finalizing a policy to maintain assigning the current RF of the lowest physician specialty (allergy/immunology), which is a RF of 1.00 to NPP specialties. We are finalizing our proposal to include an additional column on the anticipated low volume specialty list which specifies if a service was identified as a low volume service for CY 2020, indicating if the service-level override was being applied for CY 2020. We are finalizing our proposal to treat excluded specialties in a consistent manner for the purposes of calculating MP RVUs.

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). We discuss the localities established under the PFS below in this section. Although the statute requires that the PE and MP GPCIs reflect full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2017. Section 50201 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123,

enacted February 9, 2018) amended the statute to extend the 1.0 floor for the work GPCIs through CY 2019 (that is, for services furnished no later than December 31, 2019).

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. Therefore, since the previous GPCI update was implemented in CYs 2017 and 2018, we proposed to phase in ½ of the latest GPCI adjustment in CY 2020.

We have completed a review of the GPCIs and are finalizing new GPCIs in this final rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each PFS locality's work, PE and MP expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As noted above, section 50201 of the BBA of 2018 extended the 1.0 work GPCI floor for services furnished only through December 31, 2019. Therefore, the final CY 2020 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. However, as required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2020. See Addenda D and E to this final rule for the CY 2020 final GPCIs and summarized GAFs available on the CMS website under the supporting documents section of the CY 2020 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

2. Payment Locality Background

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments under this system largely reflected the charging patterns of physicians, which resulted in large differences in payment for physicians' services among types of services, physician specialties and geographic payment areas.

Local Medicare carriers initially established 210 payment localities, to reflect local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. In 1994, we undertook a study that culminated in a comprehensive locality revision (based on locality resource cost differences as reflected by the GPCIs) that we implemented in 1997. The development of the current locality structure is described in detail in the CY 1997 PFS final rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). The revised locality structure reduced the number of localities from 210 to 89, and increased the number of statewide localities from 22 to 34.

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, enacted April 1, 2014) required modifications to the payment localities in California for payment purposes beginning with 2017. As a result, in the CY 2017 PFS final rule (81 FR 80265 through 80268) we established 23 additional localities, increasing the total number of PFS localities from 89 to 112. The current 112 payment localities include 34 statewide areas (that is, only one locality for the entire state) and 75 localities in the other 16 states, with 10 states having two localities, two states having three localities, one state having four localities, and three states having five or more localities. The remainder of the 112 PFS payment localities are comprised as follows: the combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands. We note that the localities generally represent a grouping of one or more constituent counties.

The current 112 fee schedule areas, also referred to as payment localities, are defined alternatively by state boundaries (statewide areas for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate locality adjusted payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a state. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74384 through 74386) for further discussion regarding additional information about locality configuration considerations.

3. GPCI Update

As required by the statute, we developed GPCIs to measure relative cost differences among payment localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). We describe the data sources and methodologies we use to calculate each of the three GPCIs below in this section. Additional information on the CY 2020 GPCI update is available in a final report, ''Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare PFS,'' on our website located under the supporting documents section for the CY 2020 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

a. Work GPCIs

The work GPCIs are designed to reflect the relative cost of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the ''long form'' was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational

Employment Statistics (OES) wage data as a replacement for the 2000 Census data. The BLS OES data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OES wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OES is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs; and for the CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed below, the employee wage component and purchased services component of the PE GPCI). Therefore, for the CY 2020 GPCI update, we used updated BLS OES data (2014 through 2017) as a replacement for the 2011 through 2014 data to compute the work GPCIs.

b. Practice Expense (PE) GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising PEs (not including MP expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2017), we used 2011 through 2014 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed previously in this section, because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the CY 2020 GPCI update, we used updated BLS OES data (2014 through 2017) as a replacement for the 2011 through 2014 data for purposes of calculating the employee wage component and purchased service index component of the PE GPCI. In calculating the CY 2020 GPCI update, for the office rent index component of the PE GPCI we used the most recently available, 2013 through 2017, American Community Survey (ACS) 5-year estimates as a replacement for the 2009 through 2013 ACS data.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million/$3 million mature claims-made policies (policies for claims made rather than losses occurring during the policy term). For the CY 2017 GPCI update, we used 2014 and 2015 malpractice premium data. The CY 2020 MP GPCI update reflects premium data presumed in effect as of December 30, 2017. We note that we finalized a few technical refinements to the MP GPCI methodology in CY 2017, and refer readers to the CY 2017 PFS final rule (81 FR 80270) for additional discussion.

d. GPCI Cost Share Weights

For CY 2020 GPCIs, we proposed to continue to use the current cost share weights for determining the PE GPCI values and locality GAFs. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that we also finalized for use in the CY 2017 GPCI update.

The GPCI cost share weights for CY 2020 are displayed in Table 15.

TABLE 15: Cost Share Weights for CY 2020 GPCI Update

Expense Category	Current Cost Share Weight	CY 2020 Cost Share Weight
Work	50.866%	50.866%
Practice Expense	44.839%	44.839%
- Employee Compensation	16.553%	16.553%
- Office Rent	10.223%	10.223%
- Purchased Services	8.095%	8.095%
- Equipment, Supplies, Other	9.968%	9.968%
Malpractice Insurance	4.295%	4.295%
Total	**100.000%**	**100.000%**

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier states effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in states determined to be frontier states. In general, a frontier state is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that have a population per square mile of less than 6. For more information on the criteria used to define a frontier state, we refer readers to the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50160 through 50161). There are no changes in the states identified as Frontier States for the CY 2020 PFS final rule. The qualifying states are: Montana; Wyoming; North Dakota; South Dakota; and Nevada. In accordance with statute, we will apply a 1.0 PE GPCI floor for these states in CY 2020.

f. Methodology for Calculating GPCIs in the U.S. Territories

Prior to CY 2017, for all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories had minimal impact on GPCIs because we used either the Hawaii GPCIs (for the Pacific territories: Guam; American Samoa; and Northern Mariana Islands) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, in the CY 2017 PFS final rule (81 FR 80268 through 80270), we finalized a policy to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We refer readers to the CY 2017 PFS final rule for a comprehensive discussion of this policy.

g. California Locality Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure increased its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure; although for the purposes of payment the actual number of localities under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational consideration.

Section 1848(e)(6)(D) of the Act defined transition areas as the fee schedule areas for 2013 that were the rest-of-state locality, and locality 3, which was comprised of Marin County, Napa County, and Solano County. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the PFS locality structure that was in place prior to CY 2017. That is, the GPCI values applicable for these areas during this transition period are a blend of what the GPCI values would have been for California under the locality structure that was in place prior to CY 2017, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represents the fourth year, the applicable GPCI values for counties that were previously in rest-of-state or locality 3 and are now in MSAs are a blend of ⅔ of the GPCI value calculated for the year under the MSA-based locality structure, and ⅓ of the GPCI value calculated for the year under the locality structure that was in place prior to CY 2017. The proportions continue to shift by ⅙ in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas are a blend of ⅚ of the GPCI value for the year under the MSA-based locality structure, and ⅙ of the GPCI value for the year under the locality structure that was in place prior to CY 2017. Beginning in CY 2022, the applicable GPCI values for counties in transition areas are the values calculated solely under the new MSA-based locality structure. For clarity, we reiterate that this incremental phase-in is only applicable to those counties that are in transition areas that are now in MSAs, which are only some of the counties in the 2013 California rest-of state locality and locality 3.

Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless for transition areas beginning with CY 2017 whereby the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the locality structure that was in place prior to CY 2017. There are a total of 58 counties in California, 50 of which are in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that are not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we finalized the policy to start by calculating the national GPCIs as if the localities that were in place prior to CY 2017 are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is implemented for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. However, since section 1848(e)(6)(B) of the Act provides for a gradual phase in of the GPCI values under the new MSA-based locality structure for California, specifically in one-sixth increments over 6 years, if we were to also apply the requirement to phase in ½ of the adjustment in year 1 of the GPCI update then the first year increment would effectively be 1/12.

Therefore, in CY 2017, we finalized a policy that the requirement at section 1848(e)(1)(C) of the Act to phase in ½ of the adjustment in year 1 of the GPCI update would not apply to counties that were previously in the rest-of-state or locality 3 and are now in MSAs that are subject to the blended phase-in as described above in this section. We reiterate that this is only applicable through CY 2021 since, beginning in CY 2022, the GPCI values for such areas in an MSA would be fully based on the values calculated under the new MSA-based locality structure for California. For a comprehensive discussion of this provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

h. Refinements to the GPCI Methodology

In the process of calculating GPCIs for the purposes of this final rule, we identified two technical refinements to the methodology that yield improvements over the current method; these refinements are applicable to the work GPCI and the employee wage index and purchased services index components of the PE GPCI. We proposed to weight by total employment when computing county median wages for each occupation code which addresses the fact that the occupation wage can vary by industry within a county. Additionally, we proposed to use a weighted average when calculating the final county-level wage index; this removes the possibility that a county index would imply a wage of 0 for any occupation group not present in the county's data. These methodological refinements yield improved mathematical precision. Additional information on the GPCI methodology and the refinements are available in the final report, ''Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare PFS'' on our website located under the supporting documents section of the CY 2020 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

i. Proposed GPCI Update Summary

As explained above in the Background section above in this section, the periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The CY 2020 updated GPCIs for the first and second year of the 2-year phase-in, along with the GAFs, are displayed in Addenda D and E to this final rule available on our website under the supporting documents section of the CY 2020 PFS final rule web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

The following is a summary of the comments we received on the GPCI proposals and our responses.

Comment: A few commenters expressed concern over the expiring work GPCI floor of 1.0. Some of the commenters stated an objection to any proposals that could have a negative impact on rural areas such as the expiration of the work GPCI floor and stated that the GPCIs needs to account for the unique practice needs of rural providers.

Response: The 1.0 work GPCI floor is established by statute and expires on December 31, 2019. We do not have the authority to extend the 1.0 work GPCI floor beyond December 31, 2019. We note that 34 states have a statewide payment locality, which means that physicians, whether in urban or rural areas, receive the same geographic adjustment thus reducing rural/urban payment differentials within a state.

Comment: A few commenters expressed support for the elimination of all GAFs under the PFS, except those designed to achieve a specific public policy goal, such as to encourage physicians to practice in underserved areas. The commenters stated that GPCIs tend to favor urban localities over their rural counterparts and works at cross purposes to the health professional shortage area (HPSA) bonus and other incentives intended to encourage and support rural physicians. The commenters also stated that rural beneficiaries would be better served if the GPCIs were eliminated from the PFS so that the HPSA bonus and other incentives are not undermined in their efforts to sustain the rural physician workforce needed to care for those beneficiaries.

Response: As previously discussed, section 1848(e)(1)(A) of the Act requires us to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three GPCI components, and section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years; and based on new data GPCI values may increase or decrease. Additionally, as noted above, 34 states have a statewide locality, thus reducing rural/urban payment differentials within a state.

Comment: One commenter stated that CMS uses salary data for individuals with 5 or more years of college, and should instead evaluate the feasibility of using salary data only from individuals with graduate degrees in the work GPCI calculations. The commenter also stated that CMS should also consider that physicians invest a portion of their compensation in the practice and that portion should not be counted as salary.

Response: We note that physicians are not one of the seven occupation groups used in the work GPCI calculation; therefore, we are unclear about the commenter's assertion that investments of a portion of a physician's salary back into the practice should not be counted as salary. As described above, and consistent with our longstanding practice, a set of occupation groups representing a variety of professionals are used in the calculation. We note that the proxy occupations currently used represent highly educated professional occupation categories, and therefore, we believe we are already including salary data for individuals with advanced degrees.

Comment: One commenter stated concern that the work GPCI does not utilize actual physician wage data, and states that CMS' statement that including physician wage data in calculating the work GPCI would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to physician wages is flawed. The commenter stated that in the era of increasing physician employment, more physicians receive a salary dependent upon local market conditions and not the portion of their patient panel on Medicare. The commenter also stated that two of the proxy professional wage categories—pharmacists, and registered nurses—are professions whose wages are also comprised, in part, of income gained from participation in the Medicare program.

Response: We note that we have long maintained that including physicians' wages in the physician work GPCI would, in effect make the physician work GPCI to some extent dependent upon Medicare payments which in turn are impacted by the indices. We do not dispute the assertion that local market conditions may also play a role in determination of a physician's salary; however, we do not believe that mitigates the potential for circularity and maintain that, still, Medicare payment is a significant determinant of physician's earnings. We also recognize that the seven proxy professional wage

categories span several different industries, including pharmacists, and registered nurses which demonstrates that the healthcare industry is represented in those proxy wage categories; however, physicians in particular are not included in those categories as previously described. We continue to believe in the majority of instances, the earnings of physicians will vary among areas to the same degree that the earnings of other professionals across an array of industries vary. We reiterate that the work GPCI is not an absolute measure of physician earnings, rather it is a measure of the relative wage differences for each locality as compared to the national average. Additionally, the work GPCI reflects only one quarter of those relative wage differences consistent with the statutory requirement as discussed previously in this section.

Comment: A few commenters stated that CMS should re-evaluate existing databases to find or develop a nationwide measure of commercial office rents for use in calculating PE GPCIs. One commenter stated that CMS should either collect true medical office expense data or alternatively use data sources available to federal agencies such as office expense data from the Federally Qualified Health Center Network.

Response: We appreciate the commenter's feedback. We note that our efforts are ongoing to identify a publicly-available, robust, nationally representative commercial rent data source that could be made available to CMS for this purpose. Further, we welcome opportunities to discuss such data sources with stakeholders and to incorporate such data, as appropriate in the GPCI calculation process, through our standard annual rulemaking process.

Comment: One commenter expressed support for the proposed methodological refinements and stated that it could yield improvements that would be beneficial to all fields of medicine.

Response: We thank the commenter for the support of our proposed methodological refinements.

Comment: A few commenters stated that the proposed refinement to the weighting of the physician work, employee wage, and purchased services indices results in inconsistent comparisons of occupational wages from one county to the next, because industry wages within an occupational group will vary from one county to the next based on employment. The commenters recommended using the previous methodology and also stated that for counties with zero inputs that we use inputs from MSAs as is done for the rent index or use the national average as used in the previous update.

Response: The use of employment weights better captures variation in median wages themselves, which is exactly what the indices are meant to reflect. As the commenter indicated, the unweighted approach captures variation in wages reported by category in an index-like manner. This is undesirable both substantively and mathematically, since it makes the GPCIs an index based on an index rather than on the underlying data of interest. We have reviewed the process for developing county-level median wages as described in the proposed rule, and continue to believe that the use of employment weights, as we proposed, is an improvement over the use of unweighted values as requested by the commenter. We intend to continue considering how measures are weighted and summarized throughout the GPCI development process and will invite public comment on any additional potential improvements we identify through future rulemaking.

Comment: A few commenters stated that they find it challenging to extract and collate the publicly-available BLS OES data (available from the BLS website), that are used for the work and PE GPCIs in a manner that enables them to reproduce the data sets used in the work GPCI and the employee wages, and purchased services components of the PE GPCI; the commenters stated that CMS should provide more detailed information in the interest of transparency.

Response: We note that we provide web links to the publicly-available data sources used in this GPCI update, the methodological parameters, as well as an overview of how we develop each GPCI component in the final report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare PFS. This practice is consistent with previous updates. However, in consideration of the commenters' concerns that navigating the publicly-available BLS OES data on the BLS website is cumbersome, we have included more detailed steps in the aforementioned report to further assist interested parties in navigating these data.

Comment: One commenter stated that the GPCIs in Hawaii do not account for the unique costs of providing medical services in Hawaii and that this will lead to an accelerating shortage of health care providers across the state of Hawaii. The commenter stated that Hawaii's unique geography makes providing care more expensive and that the cost of living ranks amongst the highest in the nation, and the data used by CMS do not reflect the cost of living. The commenter stated that it disputes the assertion that the equipment, supplies, and miscellaneous expenses component of the PE GPCI do not vary by geographic area, and therefore, do not require updating. The commenter stated that the high cost of shipping equipment plays a major part in the high cost of healthcare in Hawaii and the PEs should reflect that additional cost that exists in Hawaii and not in the mainland United States. The commenter stated that the 1.5 work GPCI floor for Alaska, and the 1.0 PE GPCI floor for the frontier states should serve as a basis for reevaluating the cost of providing medical services in Hawaii. The commenter stated that the GPCIs should be adjusted to reflect a factor at least equal to Alaska's work GPCI.

Response: We reiterate that the GPCIs, in particular the work GPCI and the PE GPCI to which the commenter refers, are based on nationally-representative and publicly-available wage data from the BLS OES for the work GPCI and employee wage and purchased services components of the PE GPCI, and the Census Bureau's ACS data for the rent index component of the PE GPCI. The GPCIs are a measure of relative resource cost differences among localities compared to the national average as informed by the data (not a measure of absolute costs). With regards to the supplies, equipment, and miscellaneous expense cost index component of the PE GPCIs, we have stated that we believe there is a national market for these items and there is not significant geographic variation in those costs, and as such we assign a value of 1.00 for this component for each locality, consistent with the national average. Stakeholders have previously indicated that shipping and transportation expenses increase the cost of acquiring medical equipment and supplies in islands relative to the mainland. We have previously attempted to locate data sources specific to geographic variation in shipping costs, and we found no comprehensive national data source for this information, and therefore, we have not been able to quantify variation in costs specific to islands as indicated by the commenter (we refer readers to 78 FR 74387 through 74388 for a detailed discussion of this issue). The commenter did not provide any data to quantify the variation. We would encourage the commenter and other stakeholders to submit data supporting this assertion for consideration in future rulemaking; specifically, we would be

interested in information regarding potential data sources for shipping costs for medical equipment and supplies that are accessible to the public, available on a national basis for both urban and rural areas, and updated regularly. We remind commenters that the work GPCI value for Alaska is not based on the data for that state, instead section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for Alaska. Similarly, section 1848(e)(1) of the Act sets a permanent PE GPCI floor of 1.0 for the frontier states. Additionally, we note that the GAF in Hawaii, displayed in Addendum D, which represents the weighted composite of each PFS localities GPCIs, is increasing in the GPCI update from CY 2019 to years 1 and 2 of the update (CY 2020 and CY 2021).

Comment: One commenter noted that the MP GPCIs changed more significantly than other GPCIs, but also acknowledged that MP accounts for a small share of average total payments so these swings generally translate into modest payment changes. The commenter urged CMS to give consideration to comments from state medical associations and other organizations representing physicians who practice in localities facing reductions to ensure that the data driving reductions are accurate.

Response: We note that larger changes in MP GPCI values in an update year are not unprecedented, and the commenter has correctly characterized that changes in MP will equate to minimal changes in payment because MP represents a small share of average total payments. As discussed in section II.C of this final rule, there were several proposed methodological refinements in the development of the MP premium data which underlies the MP risk factors used in determining both MP RVUs and MP GPCIs which has also contributed to some of the changes; we note that not all of those proposed methodological refinements were finalized for CY 2020, and the final MP GPCIs in Addendum E of this final rule are reflective of that.

We emphasize that we do give consideration to the public comments that we receive. We note that only a few comments were received with regards to the GPCI proposals, though during the process of developing the CY 2020 final rule GPCIs, which includes reviewing the underlying data (which are obtained from publicly-available sources as previously discussed) and reviewing our programming, we did observe the following issue. The work, PE, and MP GPCIs are based on the 2017 utilization data as described in the final report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare PFS. These data became available after the CY 2020 PFS proposed rule analytic programs had been written for these measures, but for the purposes of developing the analytic programs the CY 2016 utilization data were used as a placeholder. During the final rule development we realized an oversight whereby the 2016 utilization data had not been replaced with the 2017 utilization data for the work and PE GPCIs, though we note that for the MP GPCI, the 2017 utilization data were being used. We have resolved this issue for the final rule and all 3 GPCI components reflect the updated 2017 utilization data as described in the aforementioned report. We note that utilization data are highly correlated year to year so the effect of this change on final GPCI values was quite modest; specifically, the updated utilization data had virtually no effect on the resulting work, PE, and MP GPCIs and the GAFs. Outside of California (see below for a discussion regarding California), the correlation coefficient between each of the three GPCIs and the GAF in the proposed rule, and their corresponding values in the final rule is 0.999.

Comment: A few commenters expressed concern with regards to the county rent indices delineated in the county-level data public use file whereby they noted consistent discrepancies in New England states as compared to the rest of the country. The commenters stated that before finalizing the PE GPCIs, CMS should review the indices to ensure that the relative differences in the indices accurately reflect the relative differences in rents from the source data file. One of the commenters indicated that this issue is not observed in any areas outside of New England.

Response: We note that during the review of the underlying data and analytic programs for the final rule, we identified an issue with the data in New England (Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, and Connecticut) where the raw data values were defined at sub-county areas in New England, but were not summarized to the county-level in the development of the proposed CY 2020 GPCI values. This led to distorted office rent index values for the six states in New England, which in turn affected the proposed PE GPCIs in those states. The CY 2020 PFS final rule office rent index that underlies the PE GPCI has been corrected so that the input data element is now summarized at the county-level *before* being used to develop the index. Similar to the aforementioned update to the utilization data, the corrected mapping of raw data values in New England as described above had virtually no effect on the resulting work, PE, and MP GPCIs and the GAFs. Outside of California (see below for a discussion regarding California), the correlation coefficient between each of the three GPCIs and the GAF in the proposed rule, and their corresponding values in the final rule is 0.999.

Comment: One commenter expressed concern with the implementation of the GPCI requirements in California consistent with section 1848(e)(6) of the Act which was implemented in the CY 2017 PFS final rule (81 FR 80261 through 80270). The commenter requested that CMS remedy any errors in the GPCI values. Specifically, the commenter indicated that CMS did not accurately implement the California MSA-based structure in the CY 2020 PFS proposed rule consistent with the methodology finalized in CY 2017 based on the requirements of the statute. The commenter specifically highlighted issues with the GPCIs for the San Francisco-Oakland-Hayward localities (localities 05, 06, 07, and 53); the San Jose-Sunnyvale-Santa Clara localities (localities 09, and 65); and the Los Angeles-Long Beach-Anaheim localities (localities 26, and 18). The commenter provided their analysis with their commenter letter, and stated that based on their findings, the proposed GPCIs for the nine counties contained in the eight aforementioned localities are inaccurate. The commenter also requested that CMS provide the traditional source data for the PE rent and wage indices or the relative value units (RVUs) by county that have been published in the past. Aside from the issues with these eight localities as described above, the commenter indicated that for the remaining California localities, they support and agree with the proposed GPCIs and commend CMS for accurately completing the difficult calculations as required by statute.

Response: We appreciate the analysis provided by the commenter with regards to the eight aforementioned localities and thank the commenter for bringing this to our attention. We agree with the commenter that there were issues with the calculation of the GPCI values reflected in the CY 2020 PFS proposed rule for California. In the programming, we inadvertently used the 32 MSA-based localities for which current GPCIs are defined to account for different treatment of some counties within MSAs when creating the new GPCIs, as opposed to using the 27 MSA-based localities to determine the new MSA-based payment area GPCI amounts. Additionally, we identified a

sequencing issue in our programming that led to issues in establishing the transition values and applying the hold harmless provision. We apologize for the confusion caused by these issues and have resolved these programming issues and recalculated the California GPCIs. The final CY 2020 GPCI values in California reflect the transition and hold harmless provisions executed in the proper order based on the requirements of the law. In summary, in California the issue was the level of aggregation used to create the proposed rule values, which erroneously resulted in different proposed rule values for counties within payment localities where there should not be any differences. Correcting this, along with other changes in the final rule relative to the proposed rule, led to GAFs that are higher in all but three of the 32 payment localities in California. In those three, the GAF is lower because it is now correctly equal among non-transition counties within the new MSA-based payment areas; these three counties had higher values when erroneously calculated as individual payment localities in the proposed rule than they have when correctly averaged within the MSA for the final rule GPCIs. The final rule GAFs for these three areas are lower than those published in the proposed rule by 0.1 percent in locality 26 (Los Angeles-Long Beach-Anaheim (Orange cty)), 1.4 percent in locality 05 (San Francisco-Oakland-Hayward (San Francisco cty)), and 1.8 percent in locality 06 (San Francisco-Oakland-Hayward (San Mateo cty)), but all three localities have CY 2020 PFS final rule GAFs that are higher than their current CY 2019 values. In the other 29 California payment localities, the increase in final rule GAFs relative to the proposed rule values ranges from 0.5 percent to 6.2 percent, with 13 areas experiencing an increase of 1.2 percent.

Additionally, we note that we have provided a county-level GPCI data file as one of the GPCI public use files in the downloads section of the CY 2020 PFS final rule on the CMS website, that delineates the requested source data, as well as the RVUs by county, consistent with what has been published in the past. We reiterate that the county-level data file also reflects the correction to the oversight in the proposed rule whereby we inadvertently used the 2016 utilization data for the work and PE GPCIs (though we correctly used the 2017 utilization data for the MP GPCIs) as previously discussed.

Comment: One commenter stated that for CY 2020 in California there should be 29 distinct fee schedule areas and not 32 fee schedule areas as finalized when this provision was implemented in CY 2017. The commenter stated that some of the distinct fee schedule areas that were used during the period between CY 2017 and CY 2018 are no longer necessary. The commenter stated that Orange and Los Angeles counties, which are both in the Los-Angeles-Long Beach-Anaheim MSA, should have the same GPCI values and be one locality number instead of two. Similarly, Alameda, Contra Cosa, San Francisco and San Mateo counties (all in the San Francisco-Oakland-Hayward MSA) should be identified by one locality number instead of three, and the San Francisco-Oakland-Hayward (Marin cnty) locality would remain its own distinct locality number.

Response: There are 27 MSAs in California, and when CMS implemented the MSA-based locality structure for California as discussed above, for operational considerations, we finalized 32 unique MSA-based locality numbers. We did not propose to make changes to the number of unique locality numbers for California for CY 2020. Since two of the MSAs that required multiple unique locality numbers (San Francisco-Oakland-Hayward, and San Jose-Sunnyvale-Santa Clara) to address operational considerations as described in the CY 2017 PFS final rule (81 FR 80265 through 80268) contain both transition and non-transition counties, we would still need to maintain some unique locality numbers. We remind the commenter that though starting in CY 2022, the applicable GPCIs for counties in transition areas will be calculated solely under the MSA-based locality structure as described above, the statutorily-required hold-harmless provision for counties in transition areas is permanent.

With regards to the Los Angeles-Long Beach-Anaheim MSA, which contains 2 counties (across two unique locality numbers: 18 and 26) that are not transition areas, we acknowledge that the Los Angeles-Long Beach-Anaheim MSA only needed separate unique locality numbers, for payment purposes, in year 1 (CY 2017) of the implementation of the MSA-based structure as neither of the counties in the MSA (Orange nor Los Angeles counties) are transition counties (and therefore, are not subject to aforementioned the one-sixth incremental phase-in nor hold-harmless provision). We will consider the feasibility of assigning one locality number for that MSA in future rulemaking since there will be no difference in the GPCI values, for payment purposes, for those localities going forward. Similarly, the San Francisco-Oakland-Hayward MSA contains four counties (across three unique locality numbers: 05, 06, and 07) that are not transition areas and will receive the same GPCI values, for payment purposes, going forward (San Francisco, San Mateo, Alameda, and Contra Costa counties). As such, we will consider the feasibility of collapsing those three unique locality numbers and assigning one unique locality number in future rulemaking. If we determine that to be operationally feasible, we would propose any changes in future rulemaking. We note that it would ultimately change the number of distinct fee schedule areas needed, for payment purposes, in California from 32 to 29 as suggested by the commenter.

Additionally, during the development of the CY 2020 PFS final rule GPCIs, we identified typographical errors in the naming conventions of four of the California MSA-based localities in Addendum D and Addendum E: Locality 05-San Francisco-Oakland-Hayward (San Francisco cnty) was listed as San Francisco; locality 06-San Francisco-Oakland-Hayward (San Mateo cnty) was listed as San Mateo; locality 07-San Francisco-Oakland-Hayward (Alameda/Contra Costa cnty) was listed as Oakland/Berkeley; and San Jose-Sunnyvale-Santa Clara (Santa Clara cnty) was listed as Santa Clara. This display issue has been corrected in Addendum D and Addendum E for the final rule.

Comment: One commenter stated that it believes large cuts to rural and rest-of-state areas should be avoided or minimized, but locality boundaries with large payment differences should not be in the middle of urban areas, because they create payment cliffs where payment can change if an office is moved across a street or down a block. The commenter stated that CMS should create locality definitions that are not constrained by county boundaries, and advocated implementing locality definitions based on Metropolitan Statistical Areas.

Response: We appreciate the suggestions for revisions to the PFS locality structure; however, we did not propose any changes to the PFS locality structure and decline to do so at this time. Further, we clarify that just as the localities under the locality structure used in the PFS are comprised of one or more constituent counties, so are Metropolitan Statistical Areas. Therefore, the concept of a payment cliff between neighboring counties as described by the commenter would not necessarily be mitigated by a change from PFS fee schedule areas to Metropolitan Fee Schedule Areas.

After consideration of the comments, we are finalizing the CY 2020 GPCI update, and the methodological refinements as proposed. The final GPCIs and summarized GAFs in Addenda D and E to this final rule also reflect the correction of the underlying programming issues described above.

E. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.N. of this final rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the RUC, MedPAC, and other stakeholders. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE declines. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous

potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well. Individuals and stakeholder groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox *MedicarePhysicianFeeSchedule@cms.hhs.gov,* with the phrase ''Potentially Misvalued Codes'' in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare and Medicaid Service, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes''. Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; Final Rule (76 FR 73052 through 73055) (hereinafter referred to as the ''CY 2012 PFS final rule with comment period''). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (77 FR 68892) (hereinafter referred to as the ''CY 2013 PFS final rule with comment period''), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule (73 FR 38589) (hereinafter referred to the ''CY 2009 PFS proposed rule''), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time).

In the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 final rule with comment period (80 FR 70886) (hereinafter referred to as the ''CY 2016 PFS final rule with comment period''), we finalized for review a list of potentially misvalued services, which included eight codes in the neurostimulators analysis-programming family (CPT codes 95970–95982). We also finalized as potentially misvalued 103 codes identified through our screen of high expenditure services across specialties.

In the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements final rule (81 FR 80170) (hereinafter referred to as the ''CY 2017 PFS final rule''), we finalized for review a list of potentially misvalued services, which included eight codes in the end-stage renal disease home dialysis family (CPT codes 90963–90970). We also finalized as potentially misvalued 19 codes identified through our screen for 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25.

In the CY 2018 PFS final rule, we finalized arthrodesis of sacroiliac joint (CPT code 27279) as potentially misvalued. Through the use of comment solicitations with regard to specific codes, we also examined the valuations of other services, in addition to, new potentially misvalued code screens (82 FR 53017 through 53018).

3. CY 2020 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: Technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a

misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.

- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

We received three submissions that nominated codes for review under the potentially misvalued code initiative, prior to our February 10, 2019 deadline. In addition to three public nominations, CMS also nominated one additional code for review.

One commenter requested that CMS consider CPT code 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*) for nomination as potentially misvalued. We note that these two CPT codes were recently reviewed within a family of 13 similar codes. Our review of these codes and our rationale for finalizing the current values are discussed extensively in the CY 2019 PFS final rule (83 FR 59517). For CPT code 10021, the RUC recommended a 32 percent reduction from its previous physician time and a 5 percent reduction in the work RVU. The commenter disagreed with this change and stated that there was a change in intensity of the procedure now as compared to what it was in 1995 when this code was last evaluated. The commenter also stated that there was a change in intensity of the work performed due to use of more complicated equipment, more stringent specimen sampling that allow for extensive examination of smaller and deeper lesions within the body. The commenter disagreed with the CMS' crosswalked CPT code 36440 (*Push blood transfusion, patient 2 years or younger*) and presented CPT codes 40490 (*Biopsy of lip*) and 95865 (*Needle measurement and recording of electrical activity of muscles of voice box*) as more appropriate crosswalks.

Another commenter requested that CMS consider HCPCS code G0166 (*External counterpulsation, per treatment session*) as potentially misvalued. This code was reviewed for the CY 2019 PFS final rule (83 FR 59578), and the work RVU and direct PE inputs as recommended by the AMA RUC were finalized by CMS. We finalized the valuation of this code with no refinements. However, the commenter noted that the PE inputs that were considered for this code did not fully reflect the total resources required to deliver the service. We stated we would review the commenter's submission of additional new data and public comments received in combination with what was previously presented in the CY 2019 PFS final rule.

CMS nominated CPT code 76377 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation*) as potentially misvalued. CPT code 76376 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*) was reviewed by the AMA RUC at the April 2018 RUC meeting. However, CPT code 76377, which is very similar to CPT code 76376, was not reviewed, and is likely now misvalued, in light of the similarities between the two codes. The specialty societies noted that the two codes are different because they are utilized by different patient populations (as evidenced by the ICD–10 diagnoses); however, we view both codes to be similar enough that CPT code 76377 should be reviewed to maintain relativity in the code family.

We have received and reviewed all public comments to all these codes that were nominated as potentially misvalued. Below, we present the summarizations of all these public comments.

Comment: One commenter provided information to CMS in which they stated that the work involved in furnishing services represented by the office/outpatient E/M code set (CPT codes 99201–99215) has changed sufficiently to warrant revaluation. Specifically, the commenter stated that these codes have not been reviewed in over 12 years and in that time have suffered passive devaluation as more and more procedures and other services have been added to the CPT code set, which are subsequently valued in a budget neutral manner, through notice and comment rulemaking, on the Medicare PFS. The commenter also stated that re-evaluation of these codes is critical to the success of CMS' objective of advancing value-based care through the introduction of Advanced Alternative Payment Models (APMs) as these APMs rely on the underlying E/M codes as the basis for payment or reference price for bundled payments.

Response: We acknowledge the points made by the commenter regarding the valuation of E/M codes for office and outpatient visits. We agreed, in principle, that the existing set of office/outpatient E/M CPT codes may not be correctly valued. In recent years, we have specifically considered how best to update and revalue the E/M codes, which represent a significant proportion of PFS expenditures, and have also engaged in ongoing dialogue with the practitioner community. In the CY 2019 PFS proposed and final rules, in part due to these ongoing stakeholder discussions, we proposed and finalized changes to E/M payment and documentation requirements to implement policy objectives focused on reducing provider documentation burden (83 FR 59625).

As we stated in the proposed rule, concurrently, the CPT Editorial Panel, under similar policy objectives, convened a workgroup and proposed to refine the existing E/M office/outpatient code set. Shortly thereafter, the AMA RUC revalued these services and submitted recommendations to CMS for review. In the CY 2020 PFS proposed rule, we considered the RUC-recommended values for office/outpatient E/M codes in proposing new values for CY 2021. For more detail on our review and consideration of the revalued office/outpatient E/M services please refer to section II.P of this final rule.

Table 16 lists the HCPCS and CPT codes that we proposed as potentially misvalued.

TABLE 16: HCPCS and CPT Codes Proposed as Potentially Misvalued

CPT/HCPCS Code	Short Description
10005	Fna bx w/us gdn 1st les
10021	Fna bx w/o img gdn 1st les
76377	3d render w/intrp postproces
G0166	Extrnl counterpulse, per tx

We received public comments on the HCPCS and CPT codes that we proposed as potentially misvalued. The following is a summary of the comments we received and our responses.

Comment: Several commenters submitted comments about HCPCS code G0166 and claimed that in the CY 2019 PFS final rule, CMS did not have the complete list of inputs for this ''Practice Expense only'' code, which resulted in an under-valuation of its payment.

Response: We note that the AMA RUC in its comment letter to the proposed rule informed CMS that it would review this service and forward any recommendations to CMS for review. We will review the AMA RUC's forthcoming recommendations and will consider any refinements to the valuation for this code through our standard rulemaking process for CY 2021.

Comment: Several commenters highlighted the payment reduction to code G0166 in CY 2019 relative to CY 2018 and requested that CMS revert back to the CY 2018 payment. Commenters also noted that the current and reduced payment may endanger continued offering of this service, particularly to beneficiaries with coronary artery disease with angina for whom surgical intervention may not be appropriate and where medications have proved to be ineffective.

Response: We acknowledge the receipt of all comments related to HCPCS code G0166 outlining that it may be inaccurately valued. We have reviewed the information included in the comments received, and look forward to reviewing the AMA RUC recommendations for this service. We will review the AMA RUC's forthcoming recommendations and will consider any refinements to the valuation for this code through our standard rulemaking process for CY 2021.

We refer readers to section II.B of this final rule for details on the limited updates to the supply and equipment pricing for HCPCS code G0166.

Comment: Several commenters responded to the inclusion of CPT codes 10005 and 10021 on the potentially misvalued codes list, with the majority urging CMS to revise the CY 2019 finalized RVUs by adopting the higher RUC recommended RVUs.

Response: We appreciate commenters' perspective on the valuation of CPT codes 10005 and 10021 but refer the commenters to our CY 2019 PFS final rule for our review of the relevant inputs and RUC recommendations for these codes. We have reviewed the comments received, including any additional information in response to our discussion of these codes under the potentially misvalued code initiative. We believe our refinements to the valuations for these services continue to be valid, as no new compelling information has been presented.

Comment: Commenters disagreed with using the crosswalked CPT code 36440 as the reference code for valuing CPT code 10021, even though the physician work times for both codes are very similar. One commenter stated that the previous values for work time (1995) were also based on a crosswalk (CPT codes 88170 and 88171) and not a survey, and therefore, the decrease in work time did not warrant a proportional change in work RVU as the previous times were inaccurate. Also, as discussed in the CY 2019 PFS final rule with comment period (83 FR 59517), commenters stated that the work intensity for both codes are unequal as well their incongruous procedure descriptors, pointing out the fact that CPT codes 36440, 88170, and 88171 are clinically very different to CPT code 10021.

Response: As we have discussed in previous rules, we agree that it is important to use the most recent data available regarding time, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we continue to believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times, and it also would undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS. Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times used in the PFS ratesetting processes are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. We continue to disagree with commenters' distinction of different types of physician work times as being better or worse in their measure of validity in comparison to each other, and believe that CPT code 36440 is a good comparable code to CPT code 10021 in physician work and physician work times.

Comment: For CPT code 10021, one commenter disagreed with CMS maintaining the code's global indicator of ''XXX'' (global concept does not apply) and recommended a change to ''000'' (minor surgery/zero day global).

Response: We did change the multiple procedure indicator for CPT code 10021 from a ''0'' (payment rules do not apply) to a ''2'' (standard payment adjustments do apply), but as we stated in CY 2019 PFS final rule (83 FR 59520), we do not agree that it would have been more accurate to use codes with a 0-day global period as references for the codes in this family, and the multiple procedure policy continues to apply for CPT code 10021.

In concluding our review of all the comments submitted for the nominated potentially misvalued CPT codes of 10005 and 10021, we do not believe we have received any additional

information to consider in the context of our previous review of these services. Therefore, we are not including CPT codes 10005 and 10021 on our final list of potentially misvalued codes for CY 2020.

Comment: One commenter noted on the CMS nominated CPT code 76377 (which we found to be very similar to CPT code 76376 that was AMA RUC reviewed for CY 2020), that although both code descriptors are similar, they have different clinical indications, different patients, different complexity in the work and require different resources and equipment, and that CPT code 76377 was not identified on any of the normal screens.

Response: CMS' nominated CPT code 76377 as potentially misvalued due to its similarity to CPT code 76376 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*), which is reviewed and finalized for 2020. Due to the refinements made to CPT code 76376, CPT code 76377 should be similarly reviewed to resolve the two codes' likely discrepancies. We will consider the valuation of this code in future rulemaking. During this review, we will determine if the clinical indications, the complexity of the work, and the resources that are required, are similar or different for both of these codes.

Comment: We received several comments regarding the AMA RUC's survey and recommended values for the E/M office/outpatient evaluation and management codes (99201–99015) for CY 2021.

Response: We refer readers to section II. P. of this final rule where we discuss these codes in detail.

After consideration of the comments received, in summary, we are including CPT code 76377 and HCPCS code G0166 on our final list of potentially misvalued codes for CY 2020. However, we are not including CPT codes 10005 and 10021 on our final list of potentially misvalued codes for CY 2020.

4. Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System (Category III CPT codes 0446T, 0447T, and 0448T)

Category III CPT codes 0446T, 0447T, and 0448T describe the services related to the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor from subcutaneous pocket, in a subcutaneous pocket via incision. The implantable interstitial glucose sensors are part of systems that can allow real-time glucose monitoring, provides glucose trend information, and signal alerts for detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

Diabetes is the sixth leading cause of death in the United States, and approximately 20 million Americans have diabetes with an estimated 20.9 percent of the senior population age 60 and older being affected. Millions of people have diabetes and do not know it. Left undiagnosed, diabetes can lead to severe complications such as heart disease, stroke, blindness, kidney failure, leg and foot amputations, and death related to pneumonia and flu. Scientific evidence now shows that early detection and treatment of diabetes with diet, physical activity, and new medicines can prevent or delay much of the illness and complications associated with diabetes. As with management of other chronic conditions, we believe innovative technologies that provide improved data to physicians and patients can be important tools in promoting patient-centered care.

The codes that describe the implantation, removal, and removal and implantation of implantable interstitial glucose sensors are currently contractor-priced. Since the publication of the CY 2020 PFS proposed rule, we have become aware that the contractor pricing for these services has contributed to significant confusion in the community with regards to Medicare payment rules for these kinds of monitoring systems. We understand that this confusion has led to inhibited access to these services for Medicare beneficiaries.

Given the immediate needs of Medicare beneficiaries with diabetes, including some who could benefit from these innovative technologies, we are seeking information from stakeholders to ensure proper payment for this important physician's service by establishing national payment rates in future rulemaking.

We are seeking information from stakeholders on the resources involved in furnishing the services described by Category III CPT codes 0446T *(Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training),* 0447T *(Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision),* and 0448T *(Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation).* We are specifically seeking recommendations, including the work RVUs, work time, and direct PE inputs, associated with the resources involved in inserting and removing the device, as well as the resource costs of the implantable device and disposable supplies (that is, the supply costs of the implantable device ''implantable interstitial glucose sensor'', and the smart transmitter).

Under our existing policies, we welcome recommendations on appropriate valuation for these services and any recommendations submitted by February 10, 2020 would be considered for CY 2021 PFS rulemaking.

F. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in this rule and in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. For further details, *see* the full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and in 42 CFR 410.78 and 414.65.

1. Adding Services to the List of Medicare Telehealth Services

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services in accordance with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us. Under this process, we assign any submitted request to add to the list of telehealth services to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current list of

telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The list of telehealth services, including the additions described later in this section, can be located on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

Historically, requests to add services to the list of Medicare telehealth services had to be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. However, beginning in CY 2019 we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC. For example, to be considered during PFS rulemaking for CY 2021, requests to add services to the list of Medicare telehealth services must be submitted and received by February 10, 2020. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the list of Medicare telehealth services, requesters should be advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the list of Medicare telehealth services, including where to mail these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

2. Requests To Add Services to the List of Telehealth Services for CY 2020

Under our current policy, we add services to the telehealth list on a Category 1 basis when we determine that they are similar to services on the existing telehealth list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

We did not receive any requests from the public for additions to the Medicare Telehealth list for CY 2020. We believe that the vast majority of services under the PFS that can be appropriately furnished as Medicare telehealth services have already been added to the list.

However, we proposed adding three new HCPCS G codes describing new bundled services for treatment of opioid use disorders in section II.H. of the CY 2020 PFS proposed rule which we noted are sufficiently similar to services currently on the telehealth list to be added on a Category 1 basis. Therefore, we proposed to add the face-to-face portions of the following services to the telehealth list on a Category 1 basis for CY 2020:

- HCPCS code G2086: *Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code G2087: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code G2088: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

We note that in the CY 2020 PFS proposed rule (84 FR 40518), we referred to these services using placeholder codes, HCPCS codes GYYY1, GYYY2, and GYYY3, which are being replaced with the final G codes above. Similar to our addition of the required face-to-face visit component of TCM services to the Medicare Telehealth list in the CY 2014 PFS final rule with comment period (78 FR 74403), since HCPCS codes G2086, G2087, and G2088 include face-to-face psychotherapy services, we believe that the face-to-face portions of these services are sufficiently similar to services currently on the list of Medicare telehealth services for these services to be added under Category 1. Specifically, we believe that the psychotherapy portions of the bundled codes are similar to the psychotherapy codes described by CPT codes 90832 and 90853, which are currently on the Medicare telehealth list. We note that like certain other non-face-to-face PFS services, the other components of HCPCS codes G2086–G2088 describing care coordination are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, we do not need to consider whether the non-face-to-face aspects of HCPCS codes G2086–G2088 are similar to other telehealth services. Were these components of HCPCS codes G2086–G2088 separately billable, they would not need to be on the Medicare telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology. We also note that by considering the face-to-face portion of these services to be eligible for telehealth services, the originating site facility fee could be reported, consistent with all other rules, when these services are furnished via telehealth.

As discussed in the CY 2019 PFS final rule (83 FR 59496), we note that section 2001(a) of the SUPPORT Act (Pub. L. 115–271, October 24, 2018) amended section 1834(m) of the Act, adding a new paragraph (7) that removes the geographic limitations for telehealth services furnished on or after July 1, 2019, for individuals diagnosed with a

substance use disorder (SUD) for the purpose of treating the SUD or a co-occurring mental health disorder. Section 1834(m)(7) of the Act also allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. Section 2001(a) of the SUPPORT Act additionally amended section 1834(m) of the Act to require that no originating site facility fee will be paid in instances when the individual's home is the originating site. We believe that adding HCPCS codes G2086, G2087, and G2088 to the Medicare telehealth list will complement the existing policies related to flexibilities in treating SUDs.

We note that we welcome public nominations for additions to the Medicare telehealth list. More information on the nomination process is posted under the Telehealth section of the CMS website, which can be accessed at the following web address *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

We received public comments on the proposed HCPCS codes for addition to the telehealth list on a Category 1 basis. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported our proposal to add HCPCS codes G2086, G2087, and G2088 to the Medicare telehealth list, although a few disagreed, stating that these services should only be furnished in person.

Response: We thank the commenters for their support and feedback. We note that the psychotherapy services that are included in this bundled payment are already on the list of Medicare telehealth services. After consideration of the comments received, we are finalizing our proposal to add HCPCS codes G2086, G2087, and G2088 to the Medicare telehealth list beginning in CY 2020.

Comment: Several commenters disagreed with CMS' statement that most eligible services had been added to the Medicare telehealth list and suggested that CMS should continue to engage with stakeholders to identify other services that could be furnished via Medicare telehealth or communication technology-based services. A few commenters also provided recommendations for additional services that could be added to the Medicare telehealth list, as well as suggestions for how CMS could improve the process of requesting that services be added. Commenters reiterated as they have for many years that the statutory restrictions under section 1834(m) of the Act limit availability of telehealth services, and many encouraged CMS to utilize its demonstration authority to waive restrictions.

Response: We will continue to engage with stakeholders to identify services to add to the Medicare telehealth list and other ways to leverage technology in furnishing services under the PFS within the scope of the statute. We note that the deadline for submitting requests for additions to the Medicare Telehealth list is February 10 of the year prior to the year in which the codes could be added to the Medicare telehealth list, and any requests that are received after that time will be considered in the following year's rulemaking.

Comment: A few commenters requested that CMS allow visits with the prescribing physician for medications that require medical visits for monitoring (for example, buprenorphine) to also be furnished via telehealth.

Response: We note that the majority of the E/M visit codes are already on the Medicare telehealth list and can be furnished in addition to HCPCS codes G2086, G2087, and G2088. Specific requests for consideration of additional codes for the Medicare telehealth list should be submitted through the process outlined above. We also note that there are existing rules related to telemedicine and prescribing buprenorphine for the treatment of OUD (*https://www.hhs.gov/opioids/sites/default/files/2018-09/hhs-telemedicine-hhs-statement-final-508compliant.pdf*).

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002, at $20.00. For telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The originating site facility fee for telehealth services furnished in CY 2019 is $26.15. The MEI increase for 2020 is 1.9 percent and is based on the most recent historical update of the MEI through 2019Q2 (2.4 percent), and the most recent historical multifactor productivity adjustment (MFP) through calendar year 2018 (0.5 percent). Therefore, for CY 2020, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $26.65. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period is shown in Table 17.

TABLE 17: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI Increase	Facility Fee
10/01/2001–12/31/2002	N/A	$20.00
01/01/2003–12/31/2003	3.0	$20.60
01/01/2004–12/31/2004	2.9	$21.20
01/01/2005–12/31/2005	3.1	$21.86
01/01/2006–12/31/2006	2.8	$22.47
01/01/2007–12/31/2007	2.1	$22.94
01/01/2008–12/31/2008	1.8	$23.35
01/01/2009–12/31/2009	1.6	$23.72
01/01/2010–12/31/2010	1.2	$24.00
01/01/2011–12/31/2011	0.4	$24.10
01/01/2012–12/31/2012	0.6	$24.24
01/01/2013–12/31/2013	0.8	$24.43
01/01/2014–12/31/2014	0.8	$24.63
01/01/2015–12/31/2015	0.8	$24.83
01/01/2016-12/31/2016	1.1	$25.10
01/01/2017-12/31/2017	1.2	$25.40
01/01/2018-12/31/2018	1.4	$25.76
01/01/2019-12/31/2019	1.5	$26.15
01/01/2020-12/31/2020	1.9	$26.65

G. Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Overview

Opioid use disorder (OUD) and deaths from prescription and illegal opioid overdoses have reached alarming levels. The Centers for Disease Control and Prevention (CDC) estimated 47,000 overdose deaths were from opioids in 2017 and 36 percent of those deaths were from prescription opioids.[1] OUD has become a public health crisis. On October 26, 2017, Acting Health and Human Services Secretary, Eric D. Hargan declared a nationwide public health emergency on the opioid crisis as requested by President Donald Trump.[2] This public health emergency was renewed by Secretary Alex M. Azar II on January 24, 2018, April 24, 2018, July 23, 2018, and October 21, 2018, January 17, 2019, April 19, 2019, July 17, 2019, and most recently, October 16, 2019.[3]

The Medicare population, including individuals who are eligible for both Medicare and Medicaid, has the fastest growing prevalence of OUD compared to the general adult population, with more than 300,000 beneficiaries diagnosed with OUD in 2014.[4] An effective treatment for OUD is known as medication-assisted treatment (MAT). The Substance Abuse and Mental Health Services Administration (SAMHSA) defines MAT as the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder (SUD), including OUD (§ 8.2). Currently, Medicare covers medications for MAT, including buprenorphine, buprenorphine-naloxone combination products, and extended-release injectable naltrexone under Part B or Part D, but does not cover methadone. Medicare also covers counseling and behavioral therapy services that are reasonable and necessary and furnished by practitioners that can bill and receive payment under Medicare.

Historically, Medicare has not covered methadone for MAT because of the unique manner in which this drug is dispensed and administered. Medicare Part B covers physician-administered drugs, drugs used in conjunction with durable medical equipment, and certain other statutorily-specified drugs. Medicare Part D covers drugs that are dispensed upon a prescription by a pharmacy. Methadone for MAT is not a drug administered by a physician under the ''incident to'' benefit like other MAT drugs (that is, implanted buprenorphine or injectable extended-release naltrexone) and therefore has not previously been covered by Medicare Part B. Methadone for MAT is also not a drug dispensed by a pharmacy like certain other MAT drugs (that is buprenorphine or buprenorphine-naloxone combination products) and therefore is not covered under Medicare Part D. Methadone for MAT is a schedule II controlled substance that is highly regulated because it has a high potential for abuse which may lead to severe psychological or physical dependence. As a result, methadone for MAT can only be dispensed and administered by an opioid treatment program (OTP) as provided under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) and 42 CFR part 8. Additionally, OTPs, which are healthcare entities that focus on providing MAT for people diagnosed with OUD, were not previously entities that could bill and receive payment from Medicare for the services they furnish. Therefore, there has historically been a gap in Medicare coverage of MAT for OUD since methadone (one of the three Food and Drug Administration (FDA)-approved drugs for MAT) has not been covered.

Section 2005 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018) added a new

[1] *https://www.cdc.gov/drugoverdose/data/index.html.*

[2] *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[3] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-16oct2019.aspx.*

[4] *https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2535238.*

section 1861(jjj) to the Act, establishing a new Part B benefit category for OUD treatment services furnished by an OTP beginning on or after January 1, 2020. Section 1861(jjj)(1) of the Act defines OUD treatment services as items and services furnished by an OTP (as defined in section 1861(jjj)(2) of the Act) for treatment of OUD. Section 2005 of the SUPPORT Act also amended the definition of ''medical and other health services'' in section 1861(s) of the Act to provide for coverage of OUD treatment services and added a new section 1834(w) to the Act and amended section 1833(a)(1) of the Act to establish a bundled payment to OTPs for OUD treatment services furnished during an episode of care beginning on or after January 1, 2020.

OTPs must have a current, valid certification from SAMHSA to satisfy the Controlled Substances Act registration requirement under 21 U.S.C. 823(g)(1). To obtain SAMHSA certification, OTPs must have a valid accreditation by an accrediting body approved by SAMHSA, and must be certified by SAMHSA as meeting federal opioid treatment standards in § 8.12. There are currently about 1,700 OTPs nationwide.[5] All states except Wyoming have OTPs. Approximately 74 percent of patients receiving services from OTPs receive methadone for MAT, with the vast majority of the remaining patients receiving buprenorphine.[6]

Many payers currently cover MAT services for treatment of OUD. Medicaid[7] is one of the largest payers of medications for SUD, including methadone for MAT provided in OTPs.[8] OUD treatment services and MAT are also covered by other payers such as TRICARE and private insurers. TRICARE established coverage and payment for MAT and OUD treatment services furnished by OTPs in late 2016 (81 FR 61068). In addition, as discussed in the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020'' final rule, many qualified health plans covered MAT medications for plan year 2018 (84 FR 17536).

In the CY 2019 PFS final rule (83 FR 59497), we included a Request for Information (RFI) to solicit public comments on the implementation of the new Medicare benefit category for OUD treatment services furnished by OTPs established by section 2005 of the SUPPORT Act. We received 9 public comments. Commenters were generally supportive of the new benefit and expanding access to OUD treatment for Medicare beneficiaries. We received feedback that the bundled payments to OTPs should recognize the intensity of services furnished in the initiation stages, durations of care, the needs of patients with more complex needs, costs of emerging technologies, and use of peer support groups. We also received feedback that costs associated with care coordination among the beneficiary's practitioners should be included in the bundled payment given the myriad of health issues beneficiaries with OUD face. We considered this feedback as we developed our proposals for implementing the new benefit category for OUD treatment services furnished by OTPs and the proposed bundled payments for these services.

To implement section 2005 of the SUPPORT Act, we proposed to establish rules to govern Medicare coverage of and payment for OUD treatment services furnished in OTPs. We proposed to establish definitions of OUD treatment services and OTP for purposes of the Medicare Program. We also proposed a methodology for determining Medicare payment for such services provided by OTPs. We proposed to codify these policies in a new section of the regulations at § 410.67. For a discussion about Medicare enrollment requirements and the program integrity approach for OTPs, we refer readers to section III.H. in this final rule, Medicare Enrollment of Opioid Treatment Programs.

2. Definitions

a. Opioid Use Disorder Treatment Services

The SUPPORT Act amended section 1861 of the Act by adding a new subsection (jjj)(1) that defines ''opioid use disorder treatment services'' as the items and services that are furnished by an OTP for the treatment of OUD, as set forth in subparagraphs (A) through (F) of section 1861(jjj)(1) of the Act which include:

- Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 355) for use in the treatment of OUD;
- Dispensing and administration of such medications, if applicable;
- Substance use counseling by a professional to the extent authorized under state law to furnish such services;
- Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under state law);
- Toxicology testing; and
- Other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation).

As described previously, section 1861(jjj)(1)(A) of the Act defines covered OUD treatment services to include oral, injected, and implanted opioid agonist and antagonist medications approved by the FDA under section 505 of the FFDCA for use in the treatment of OUD. There are three drugs currently approved by the FDA for the treatment of opioid dependence: Buprenorphine, methadone, and naltrexone.[9] FDA notes that all three of these medications have been demonstrated to be safe and effective in combination with counseling and psychosocial support and that those seeking treatment for an OUD should be offered access to all three options as this allows providers to work with patients to select the medication best suited to an individual's needs.[10] Each of these medications is discussed below in more detail.

Buprenorphine is FDA-approved for acute and chronic pain in addition to opioid dependence. It is listed by the Drug Enforcement Administration (DEA) as a Schedule III controlled substance because of its moderate to low potential for physical and psychological dependence.[11] [12] The medication's partial agonist properties allow for its use in opioid replacement therapy, which is a process of treating OUD by using a substance, for example, buprenorphine or methadone, to substitute for a stronger full agonist opioid.[13] Buprenorphine drug products that are currently FDA-approved and marketed for the treatment of opioid dependence include oral buprenorphine tablets, oral buprenorphine with

[5] *https://dpt2.samhsa.gov/treatment/directory.aspx.*

[6] *https://wwwdasis.samhsa.gov/dasis2/nssats.htm.*

[7] Medicaid provides health care coverage to 65.9 million Americans, including low-income adults, children, pregnant women, elderly adults and people with disabilities. Medicaid is administered by states, according to federal requirements, and is funded jointly by states and the federal government. States have the flexibility to administer the Medicaid program to meet their own state needs within the Medicaid program parameters set forth in federal statute and regulations. As a result, there is variation in how each state implements its programs.

[8] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[9] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[10] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[11] *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

[12] *https://www.dea.gov/drug-scheduling.*

[13] *https://www.ncbi.nlm.nih.gov/books/NBK459126/.*

naloxone [14] films and tablets, an extended-release buprenorphine injection for subcutaneous use, and a buprenorphine implant for subdermal administration.[15] In most patients with opioid dependence, the initial oral dose is 2 to 4 mg per day with a maintenance dose of 8–12 mg per day.[16] Dosing for the extended-release injection is 300 mg monthly for the first 2 months followed by a maintenance dose of 100 mg monthly.[17] The extended-release injection is indicated for patients who have initiated treatment with an oral buprenorphine product for a minimum of 7 days.[18] The buprenorphine implant consists of four rods containing 74.2 mg of buprenorphine each, and provides up to 6 months of treatment for patients who are clinically stable on low-to-moderate doses of an oral buprenorphine-containing product.[19] Currently, federal regulations permit buprenorphine to be prescribed or dispensed by qualifying physicians and qualifying other practitioners at office-based practices and dispensed in OTPs.[20] [21]

Methadone is FDA-approved for management of severe pain in addition to opioid dependence. It is listed by the DEA as a Schedule II controlled substance because of its high potential for abuse, with use potentially leading to severe psychological or physical dependence.[22] [23] Methadone drug products that are FDA-approved for the treatment of opioid dependence include oral methadone concentrate and tablets.[24] In patients with opioid dependence, the total daily dose of methadone on the first day of treatment should not ordinarily exceed 40 mg, unless the program physician documents in the patient's record that 40 mg did not suppress opioid abstinence, with clinical stability generally achieved at doses between 80 to 120 mg/day.[25] By law, methadone used for treatment of OUD can only be dispensed through an OTP certified by SAMHSA except in certain, very limited circumstances.[26]

Naltrexone is FDA-approved to treat alcohol dependence in addition to OUD.[27] Unlike buprenorphine and methadone, which activate opioid receptors, naltrexone binds and blocks opioid receptors and reduces opioid cravings.[28] Therefore, naltrexone is not a scheduled substance; there is no abuse and diversion potential with naltrexone.[29] [30] The naltrexone drug product that is FDA-approved for the treatment of opioid dependence is an extended-release, intramuscular injection.[31] The recommended dose is 380 mg delivered intramuscularly every 4 weeks or once a month after the patient has achieved an opioid-free duration of a minimum of 7–10 days.[32] Naltrexone can be prescribed by any health care provider who is licensed to prescribe medications.[33]

We proposed that the OUD treatment services that may be furnished by OTPs include the first five items and services listed in the statutory definition described above, specifically the medications approved by the FDA under section 505 of the FFDCA for use in the treatment of OUD; the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing. We also proposed to use our discretion under section 1861(jjj)(1)(F) of the Act to include other items and services that the Secretary determines are appropriate to include the use of telecommunications for certain services, as discussed later in this section. We proposed to codify this definition of OUD treatment services furnished by OTPs at § 410.67(b). As part of this definition, we also proposed to specify that an OUD treatment service is an item or service that is furnished by an OTP that meets the applicable requirements to participate in the Medicare Program and receive payment.

We solicited comment on any other items and services (not including meals or transportation as they are statutorily prohibited) currently covered and paid for under Medicare Part B when furnished by Medicare-enrolled providers/suppliers that the Secretary should consider adding to this definition, including any evidence supporting the impact of the use of such items and services in the treatment of OUD and enumeration of their costs. We noted we were particularly interested in public feedback on whether intake activities, which may include services such as an initial physical examination, initial assessments and preparation of a treatment plan, as well as periodic assessments, should be included in the definition of OUD treatment services. Additionally, we noted that while the current FDA-approved medications under section 505 of the FFDCA for the treatment of OUD are opioid agonists and antagonist medications, other medications that are not opioid agonist and antagonist medications, including drugs and biologicals, could be developed for the treatment of OUD in the future. We solicited public feedback on whether there are any drug development efforts in the pipeline that could result in medications intended for use in the treatment of OUD with a novel mechanism of action that does not involve opioid agonist and antagonist mechanisms (that is, outside of activating and/or blocking opioid receptors). We also solicited comment on how medications that may be approved by the FDA in the future for use in the treatment of OUD with a novel mechanism of action, such as medications approved under section 505 of the FFDCA to treat OUD and biological products licensed under section 351 of the Public Health Service Act to treat OUD, should be considered in the context of OUD treatment services provided by OTPs, and whether CMS should use the discretion afforded under section 1861(jjj)(1)(F) of the Act to include such medications in the definition of OUD treatment services given the possibility that such medications could be approved in the future.

We received a number of public comments on the proposed definition of ''opioid use disorder treatment services.'' The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of including the five statutorily-required items and services in the definition of OUD treatment services: (1) Opioid agonist and antagonist treatment medications approved by the FDA for treatment of OUD; (2) dispensing and administration

[14] Naloxone is added to buprenorphine to reduce its abuse potential and limit diversion.

[15] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[16] *https://www.ncbi.nlm.nih.gov/books/NBK459126/.*

[17] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

[18] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

[19] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204442s006lbl.pdf.*

[20] *https://www.fda.gov/Drugs/NewsEvents/ucm611659.htm.*

[21] 21 U.S.C. 823(g)(2).

[22] *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

[23] *https://www.dea.gov/drug-scheduling.*

[24] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[25] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/017116s032lbl.pdf.*

[26] *https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone.*

[27] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021897s042lbl.pdf.*

[28] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.*

[29] *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

[30] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.*

[31] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[32] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021897s042lbl.pdf.*

[33] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.*

of such medications; (3) substance use counseling; (4) individual and group therapy; and (5) toxicology testing. Commenters were also generally supportive of the use of telecommunications for substance use counseling and individual and group therapy services.

Response: We thank commenters for their support of including the five statutorily-required items and services and the use of telecommunications for certain services in the definition of OUD treatment services. We are finalizing a definition of OUD treatment services that includes these items and services at § 410.67(b).

Comment: Many commenters expressed support for allowing licensed mental health professionals to directly bill Medicare for counseling and therapy services provided in an OTP. Some commenters requested clarification on whether OUD treatment services would only include substance use counseling and individual and group therapy services furnished by physicians, psychologists, and practitioners that can bill Medicare directly and not services furnished by other types of mental health professionals that are licensed by the state, such as licensed professional counselors, licensed mental health counselors, and licensed clinical professional counselors. These commenters raised concerns that only allowing physicians and psychologists to furnish these services and not including other mental health professionals authorized by the state to furnish counseling and therapy services would limit access to care due to workforce shortages. Some commenters requested that we clarify the distinction between substance use counseling and individual and group therapy services or allow these terms to be generally used interchangeably.

Response: Under sections 1861(jjj)(1)(C) and (D) of the Act, substance use counseling for OUD treatment can be provided by ''a professional to the extent authorized under State law to furnish such services,'' while individual and group therapy can be ''with a physician or psychologist (or other mental health professional to the extent authorized under State law).'' Consistent with the statute, in the proposed rule we did not propose to limit the professionals that can provide these services to physicians, psychologists, or other practitioners who can bill Medicare directly. Instead, we noted that the professionals that could provide such services could include licensed professional counselors, licensed clinical alcohol and drug counselors, and certified peer specialists that are permitted to furnish this type of therapy or counseling by state law and scope of practice. To the extent that the individuals furnishing therapy or counseling services are not authorized under state law to furnish such services, the therapy or counseling services provided by these professionals would not be covered as OUD treatment services. Regarding the commenters' request for clarification of the distinction between substance use counseling and therapy services, we are not specifying the differences between these two types of services, but would note that different types of professionals may be authorized to furnish substance use counseling versus therapy services under state law. Regarding the comments that supported allowing licensed mental health professionals to directly bill Medicare for counseling and therapy services provided in an OTP, we note that only OTPs can bill for the bundled payment for furnishing OUD treatment services.

Comment: Several commenters opined on the types of toxicology testing that should be included in the definition of OUD treatment services. One commenter recommended that we clarify the language regarding ''toxicology testing'' in the definition of OUD treatment services to include ''presumptive and definitive drug testing in line with clinical best practice'' to better de-stigmatize the use of these services. Other commenters suggested that only presumptive toxicology testing be included in the definition and that definitive testing be billed separately under the Medicare Clinical Laboratory Fee Schedule (CLFS). Alternatively, if definitive testing were to be included, commenters suggested that the bundled payment rate should be updated to reflect the cost of this type of toxicology testing by increasing the bundled payment rate or establishing add-on payments for definitive testing. Commenters raised the differences in complexities and costs between presumptive and definitive toxicology testing. These commenters explained that presumptive testing is an initial test that is conducted through point of care rapid result cup testing, which has testing and accuracy limitations. OTPs typically perform presumptive toxicology testing for drugs of abuse on-site using cups and dipsticks that indicate the presence or absence of drug classes as long as the test systems that are used are classified as waived test systems under the regulations implementing the Clinical Laboratory Improvement Amendments (CLIA) (Pub. L. 100–578, enacted October 31, 1988), as amended, 42 CFR part 493, and the OTP has a valid certificate of waiver that authorizes it to perform CLIA waived tests.

Due to limitations of presumptive testing, OTPs may also send urine samples to reference labs for definitive drug testing to make sure they know exactly which drugs have been ingested. Definitive drug testing uses liquid or gas chromatography coupled with mass spectrometry to identify hundreds of specific drugs and their metabolites. Definitive drug testing identifies and precisely quantifies specific drugs and/or metabolites that are positive in a sample. A treating physician may order a confirmatory test despite the outcome of the presumptive testing to obtain more information on the drugs that a patient is taking. Commenters raised the cost differences under the CY 2019 Medicare CLFS between the two types of tests ranging from $12.60–$64.65 for presumptive testing to $114.43–$246.92 for definitive testing. Some commenters requested clarification of the distinction between the toxicology testing that would be included in the definition of OUD treatment services and would be paid under the bundle and medically-necessary toxicology testing that is billed and paid under the Medicare CLFS.

Response: We noted in the CY 2020 PFS proposed rule that under SAMHSA certification standards at § 8.12(f)(6), OTPs are required to provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment in accordance with generally accepted clinical practice. These drug abuse tests are used for diagnosing, monitoring and evaluating progress in treatment (84 FR 40527). Consistent with the discussion of the different types of toxicology testing in the proposed rule, we are clarifying that the reference to toxicology testing in the definition of OUD treatment services includes both presumptive and definitive testing. We are also clarifying that all types of toxicology testing that are used for diagnosing, monitoring and evaluating the progress in treatment at the OTP are included in the definition of OUD treatment services and would be paid under the bundled payment. Toxicology tests that are unrelated to the care and treatment for OUD at an OTP may be paid separately under the CLFS, if reasonable and necessary, since toxicology tests for these purposes are not included in the bundled payments to OTPs. CMS expects that the ordering

practitioner would document the medical necessity for this additional testing in the beneficiary's medical record.

Comment: Many commenters supported the inclusion of intake activities, such as the initial physician examination, initial assessment and preparation of a treatment plan, as well as periodic assessments in the definition of OUD treatment services. One of the commenters noted these were significant activities performed by the treatment teams that were not included in the proposed bundle, nor are they paid for separately in the OTPs, and stated these services should be included. Another commenter stated that initial assessment and treatment planning activities are generally the first part of OUD treatment and that treatment planning cannot always be linear and must, at times, be revised. The commenter noted that these activities are typical of any substance abuse treatment program and should be included in the definition of OUD treatment services.

Response: We agree with commenters that intake activities, such as the initial physician examination, initial assessment and preparation of a treatment plan, should be included in the definition of OUD treatment services. We also agree with commenters that periodic assessment should be included in the definition of OUD treatment services. We note that an initial medical examination and both initial and periodic assessments are required under the SAMHSA regulations. Specifically, under the SAMHSA requirements at § 8.12(f)(2), OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

Under § 8.12(f)(4), OTPs are required to do initial and periodic assessments. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes: The patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services. We understand that intake activities and periodic assessments are integral services for the establishment and maintenance of OUD treatment for a beneficiary at an OTP. Therefore, we are believe it is reasonable to include these services in the definition of OUD treatment services. Accordingly, we are finalizing a revised definition of OUD treatment services in § 410.67(b) that reflects the required intake activities and periodic assessments. We discuss coding and payment for these services in the Coding section below.

Comment: A few commenters requested that CMS publish a detailed list of the items and services that are covered as OUD treatment services and would be included in the bundled payment to the OTPs.

Response: The items and services included in the definition of OUD treatment services are listed in the preamble of this final rule and in the regulations at § 410.67(b). We note that the items and services that are medically-necessary for OUD treatment could in some cases also be furnished and billed by other Medicare practitioners under another Medicare benefit category. For example, we anticipate that some beneficiaries receiving counseling or therapy as part of an OTP bundle of services may also be receiving medically reasonable and necessary counseling or therapy as part of a physician's service during the same time period. In this scenario, the counseling or therapy provided as part of a physician's service could be billed separately.

Comment: One commenter supported a definition of OUD treatment services that would allow for coverage of innovative therapies in development that have not yet been approved by the FDA for treatment of OUD. The commenter suggested changing the proposed regulatory language in § 410.67(b)(1) to ''Therapies approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug, and Cosmetic Act for use in treatment of opioid use disorder.'' A few commenters recommended that drugs used for opioid detoxification withdrawal and management maintenance such as naloxone, clonidine, and lofexidine be included in the definition of OUD treatment services.

Response: We thank the commenters for their feedback on including drugs that are not opioid agonist or antagonist medications in the definition of OUD treatment services. For CY 2020, we are finalizing a definition of OUD treatment services that reflects the statutory requirement in section 1861(jjj)(1)(A) of the Act to include opioid agonist and antagonist treatment medications approved by the FDA in the definition of OUD treatment services. We will consider these comments on additional drugs to include in the definition of OUD treatment services under our discretionary authority in section 1861(jjj)(1)(F) of the Act as we continue to work on refining this new Medicare benefit in future rulemaking.

Comment: In response to the request for comment on adding various other types of items and services to the definition of OUD treatment services, several commenters indicated that case management and care coordination are services furnished by OTPs and should be included in the definition of OUD treatment services. Some commenters also requested that peer-to-peer support, crisis management, and non-opioid alternative treatment be included in the definition of OUD treatment services. One commenter urged CMS to include Medical Nutrition Therapy services that are furnished by registered dietician nutritionists as a core component of OTPs because individuals with OUD suffer from gastrointestinal issues, eating disorders and malnutrition. The commenter stated it is essential that CMS build a payment model that leverages the different expertises of the full health care team, including registered dietician nutritionists. Another commenter urged CMS to include physical therapy within the list of OUD treatment services and recommended adjusting the bundled payment rates to account for instances in which effective treatment requires physical therapy and other nonpharmacological treatment services. Some commenters noted that the proposed bundled payment should include both e-prescribing and behavioral health information technology consultation and support services. One commenter urged that the definition of OUD treatment services include services performed by pharmacists including psychiatric pharmacists, such as medication adherence, management, and education or counseling. Some commenters suggested adding other laboratory tests, including HIV, Hepatitis, liver disease,

or infectious diseases. Other commenters noted SAMHSA requirements for treatment for tobacco use disorder, alcohol use disorder, and family services for OTPs and recommended that these should be included in the definition of OUD treatment.

Response: We appreciate the comments recommending additional types of items and services that could be added to the definition of OUD treatment services. For CY 2020, we are finalizing a definition of OUD treatment services that includes those items and services that we understand are required for all OTPs to furnish as specified in SAMHSA regulations (part 8). Because this is the first year of the OTP benefit, we believe it would be premature to include in the definition additional items and services until we have additional information regarding their use by OTPs in the treatment of Medicare beneficiaries with OUD. However, we note that the definition of OUD treatment services does not prevent an OTP from furnishing the additional items and services suggested above in accordance with best practices as clinically appropriate, SAMHSA regulations and guidance, and State law. We may consider the items and services suggested by commenters further as we continue to work on refining this new Medicare benefit in future rulemaking. Accordingly, we are interested in continued feedback and data on the specific items and services, including their frequency, furnished to beneficiaries by an OTP.

After consideration of the public comments, we are finalizing our proposal to include the five statutorily-required items and services in the definition of OUD treatment services in § 410.67(b). For the reasons discussed previously, we will also include intake activities and periodic assessments required under § 8.14(f)(4) in the definition of OUD treatment services in § 410.67(b).

b. Opioid Treatment Program

Section 2005 of the SUPPORT Act also amended section 1861 of the Act by adding a new subsection (jjj)(2) to define an OTP as an entity meeting the definition of OTP in 42 CFR 8.2 or any successor regulation (that is, a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1)), that meets the additional requirements set forth in subparagraphs (A) through (D) of section 1861(jjj)(2) of the Act. Specifically, the OTP:

- Is enrolled under section 1866(j) of the Act;
- Has in effect a certification by SAMHSA for such a program;
- Is accredited by an accrediting body approved by SAMHSA; and
- Meets such additional conditions as the Secretary may find necessary to ensure the health and safety of individuals being furnished services under such program and the effective and efficient furnishing of such services.

These requirements are discussed in more detail in this section.

(1) Enrollment

As discussed previously, under section 1861(jjj)(2)(A) of the Act, an OTP must be enrolled in Medicare to receive Medicare payment for covered OUD treatment services under section 1861(jjj)(1) of the Act. We refer the reader to section III.H. of this final rule, Medicare Enrollment of Opioid Treatment Programs, for further details on our policies related to enrollment of OTPs.

(2) Certification by SAMHSA

As provided in section 1861(jjj)(2)(B) of the Act, OTPs must be certified by SAMHSA to furnish Medicare-covered OUD treatment services. SAMHSA has created a system to certify and accredit OTPs, which is governed by part 8, subparts B and C. This regulatory framework allows SAMHSA to focus its oversight efforts on improving treatment rather than solely ensuring that OTPs are meeting regulatory criteria, and preserves states' authority to regulate OTPs. To be certified by SAMHSA, OTPs must comply with the federal opioid treatment standards as outlined in § 8.12, be accredited by a SAMHSA-approved accreditation body, and comply with any other conditions for certification established by SAMHSA. Specifically, SAMHSA requires OTPs to provide the following services:

- *General*—OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services.
- *Initial medical examination services*—OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP.
- *Special services for pregnant patients*—OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services for pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.
- *Initial and periodic assessment services*—Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment.
- *Counseling services*—OTPs must provide adequate substance abuse counseling to each patient as clinically necessary by a program counselor, qualified by education, training, or experience to assess the patient's psychological and sociological background.
- *Drug abuse testing services*—OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, defined in § 8.2 as detoxification treatment not in excess of 30 days, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

The provisions governing recordkeeping and patient confidentiality at § 8.12(g)(1) require that OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. All records are required to be kept confidential in accordance with all applicable federal and state requirements. The requirements at § 8.12(g)(2) state that OTPs shall document in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled in any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances, as determined by the medical director or program physician of the OTP in which the patient is enrolled (§ 8.12(g)(2)). Additionally, the requirements at § 8.12(h) address medication administration, dispensing, and use.

SAMHSA requires that OTPs shall ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate state law and registered under the appropriate state and federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. OTPs shall use only those

opioid agonist treatment medications that are approved by the FDA for use in the treatment of OUD. They must maintain current procedures that are adequate to ensure that the dosing requirements are met, and each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling.

At § 8.12(i), regarding unsupervised or ''take-home'' use of opioid agonist treatment medications, SAMHSA has specified that OTPs must follow requirements specified by SAMHSA to limit the potential for diversion of opioid agonist treatment medications to the illicit market when dispensed to patients as take-homes, including maintaining current procedures to identify the theft or diversion of take-home medications. The requirements at § 8.12(j) for interim maintenance treatment, state that the program sponsor of a public or nonprofit private OTP subject to the approval of SAMHSA and the state, may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. Patients in interim maintenance treatment are permitted to receive daily dosing, but take-homes are not permitted. During interim maintenance treatment, initial treatment plans and periodic treatment plan evaluations are not required and a primary counselor is not required to be assigned to the patient. The OTP must be able to transfer these patients from interim maintenance into comprehensive maintenance treatment within 120 days. Interim maintenance treatment must be provided in a manner consistent with all applicable federal and state laws.

The SAMHSA requirements at § 8.12(b) address administrative and organizational structure, requiring that an OTP's organizational structure and facilities shall be adequate to ensure quality patient care and meet the requirements of all pertinent federal, state, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director who is a physician who is licensed to practice medicine in the jurisdiction in which the OTP is located. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in part 8, subpart C, and any regulations regarding the use of opioid agonist treatment medications in the treatment of OUD that may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable federal, state, and local laws and regulations.

The provision governing patient admission criteria at § 8.12(e) requires that an OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual of Mental Disorders, that the person has had an OUD for at least 1 year before admission for treatment. If under 18 years of age, the patient is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period and have the written consent of a parent, legal guardian, or responsible adult designated by the relevant state authority, to be eligible for maintenance treatment.

To ensure continuous quality improvement, the requirements at § 8.12(c) state that an OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes, and a current Diversion Control Plan as part of its quality assurance program.

The requirements at § 8.12(d) with respect to staff credentials, state that each person engaged in the treatment of OUD must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. In addition, all physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.

In addition to meeting the criteria described above, OTPs must apply to SAMHSA for certification. As part of the conditions for certification, SAMHSA specifies that OTPs shall:

- Comply with all pertinent state laws and regulations.
- Allow inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, by the DEA, and by authorized employees of any relevant State or federal governmental authority.
- Comply with the provisions of 42 CFR part 2 (regarding confidentiality of SUD patient records).
- Notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.
- Comply with all regulations enforced by the DEA under 21 CFR chapter II, and be registered by the DEA before administering or dispensing opioid agonist treatment medications.
- Operate in accordance with federal opioid treatment standards and approved accreditation elements.

Furthermore, SAMHSA has issued additional guidance for OTPs that describes how programs can achieve and maintain compliance with federal regulations.[34]

(3) Accreditation of OTPs by a SAMHSA-Approved Accrediting Body

As provided in section 1861(jjj)(2)(C) of the Act, OTPs must be accredited by a SAMHSA-approved accrediting body in order to furnish Medicare-covered OUD treatment services. In 2001, the Department of Health and Human Services (HHS) and SAMHSA issued final regulations to establish a new oversight system for the treatment of SUDs with MAT (part 8). SAMHSA-approved accrediting bodies evaluate OTPs and perform site visits to ensure SAMHSA's opioid dependency treatment standards are met. SAMHSA also requires OTPs to be accredited by a SAMHSA-approved accrediting body (§ 8.11).

The SAMHSA regulations establish procedures for an entity to apply to become a SAMHSA-approved accrediting body (§ 8.3). When determining whether to approve an applicant as an accreditation body, SAMHSA examines the following:

- Evidence of the nonprofit status of the applicant (that is, of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a state governmental entity or political subdivision;
- The applicant's accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the federal opioid treatment standards set forth in § 8.12;
- A detailed description of the applicant's decision-making process, including:

++ Procedures for initiating and performing onsite accreditation surveys of OTPs;

[34] *https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf.*

++ Procedures for assessing OTP personnel qualifications;

++ Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process;

++ Policies and procedures for notifying OTPs and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTPs; for suspending or revoking an OTP's accreditation; and to ensure processing of applications for accreditation and for renewal of accreditation within a timeframe approved by SAMHSA; and;

++ A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions.

• Policies and procedures established by the accreditation body to avoid conflicts of interest, or the appearance of conflicts of interest;

• A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician on the applicant's staff;

• A description of the applicant's training policies;

• Fee schedules, with supporting cost data;

• Satisfactory assurances that the applicant will comply with the requirements of § 8.4, including a contingency plan for investigating complaints under § 8.4(e);

• Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body; and

• Any other information SAMHSA may require.

SAMHSA periodically evaluates the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the federal opioid treatment standards. There are currently six SAMHSA-approved accreditation bodies.[35]

(4) Provider Agreement

Section 2005(d) of the SUPPORT Act amended section 1866(e) of the Act by adding a new paragraph (3) which includes OTPs (but only with respect to the furnishing of OUD treatment services) as a ''provider of services'' for purposes of section 1866 of the Act. All providers of services under section 1866 of the Act must enter into a provider agreement with the Secretary and comply with other requirements specified in that section. These requirements are codified at 42 CFR part 489. Therefore, we proposed to amend part 489 to include OTPs (but only for furnishing OUD treatment services) as a provider. Specifically, we proposed to add OTPs (but only for the furnishing of OUD treatment services) to the list of providers in § 489.2. This addition makes clear that the other requirements specified in section 1866 of the Act, and implemented in part 489, which include the limits on charges to beneficiaries, will apply to OTPs (in connection with the furnishing of OUD treatment services). We also proposed additional changes to make clear that certain parts of part 489, which implement statutory requirements other than section 1866 of the Act, do not apply to OTPs. For example, since we did not propose any conditions of participation for OTPs, we proposed to amend § 489.10(a), which states that providers specified in § 489.2 must meet conditions of participation, to add that OTPs must meet the requirements set forth in part 489 and elsewhere in that chapter. In addition, we proposed to specify that the effective date of the provider agreement is the date on which CMS accepts a signed agreement (proposed amendment to § 489.13(a)(2)), and is not dependent on surveys or an accrediting organization's determination related to conditions of participation. As noted earlier in the preamble to this final rule, OTPs are required to be certified by SAMHSA and accredited by an accrediting body approved by SAMHSA. In § 489.53, we proposed to create a basis for termination of the provider agreement if the OTP no longer meets the requirements set forth in part 489 or elsewhere in that chapter (including if it no longer has a SAMHSA certification or accreditation by a SAMHSA-approved accrediting body). Finally, we proposed to revise 42 CFR part 498 to ensure that OTPs have access to the appeal process in case of an adverse determination concerning continued participation in the Medicare program. Specifically, we proposed to amend the definition of provider in § 498.2 to include OTPs. We also indicated that we would continue to review the application of the provider agreement requirements to OTPs to determine whether any further amendments to parts 489 and 498 were needed to ensure that the existing provider agreement regulations are applied to OTPs consistent with our proposals and section 2005 of the SUPPORT Act.

Comment: Multiple commenters questioned whether provider agreements, once executed, will be made retroactive to January 1, 2020.

Response: We proposed in § 489.13(a)(2)(i) that the effective date of an OTP provider agreement would be the date on which we accept a signed agreement that ensures that the OTP meets all federal requirements. Yet, as discussed in section III.H of the final rule we also proposed retrospective billing dates in § 424.520(d) and § 424.521(a) if the requirements of those sections were met. To ensure that the provider agreement and billing effective dates are uniform, we are not finalizing our proposed change to § 489.13(a)(2)(i). Instead, we will establish a new § 489.13(a)(2)(iii) stating that the provider agreement effective date is to be consistent with the billing effective date established pursuant § 424.520(d) or § 424.521(a), as applicable. In sum, the effective dates of OTP provider agreements will not automatically be made retroactive to January 1, 2020, but will instead be governed by § 489.13(a)(2)(iii).

After consideration of comments received, we are making changes to § 489.13(a)(2)(i) to align with the provider agreement effective date to the billing effective date under § 424.520(d) or § 424.521(a), as applicable. We did not receive any other comments on the proposals for the provider agreement requirements in §§ 489.2, 489.10, 489.43, and 498.2., and are finalizing these changes as proposed.

(5) Additional Conditions

As provided in section 1861(jjj)(2)(D) of the Act, to furnish Medicare-covered OUD treatment services, OTPs must meet any additional conditions as the Secretary may find necessary to ensure the health and safety of individuals being furnished services under such program and the effective and efficient furnishing of such services. The comprehensive OTP standards for certification of OTPs address the same topics as would be addressed by CMS supplier standards, such as client assessment and the services required to be provided. Furthermore, the detailed process established by SAMHSA for selecting and overseeing its accreditation organizations is similar to the accrediting organization oversight process that would typically be established by CMS. Thus, in the proposed rule, we stated that we believe the existing SAMHSA certification and accreditation requirements are both

[35] *https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-accrediting-bodies/approved.*

appropriate and sufficient to ensure the health and safety of individuals being furnished services by OTPs, as well as the effective and efficient furnishing of such services. We also indicated that we believe that creating additional conditions at this time for participation in Medicare by OTPs could create unnecessary regulatory duplication and could be potentially burdensome for OTPs. Therefore, we did not propose any additional conditions for participation in Medicare by OTPs in the CY 2020 PFS proposed rule. We solicited public comments on our proposed approach, including input on whether there are any additional conditions that should be required for OTPs furnishing Medicare-covered OUD treatment services.

(6) Proposed Definition of Opioid Treatment Program

We proposed to define ''opioid treatment program'' at § 410.67(b) as an entity that is an OTP as defined in § 8.2 (or any successor regulation) and meets the applicable requirements for an OTP. We proposed to codify this definition at § 410.67(b). In addition, we proposed that for an OTP to participate and receive payment under the Medicare program, the OTP must be enrolled under section 1866(j) of the Act, have in effect a certification by SAMHSA for such a program, and be accredited by an accrediting body approved by SAMHSA. We also proposed that an OTP must have a provider agreement as required by section 1866(a) of the Act. We proposed to codify these requirements at § 410.67(c). We solicited public comments on the proposed definition of OTP and the proposed Medicare requirements for OTPs.

The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the proposed definition of OTP, including the requirements that OTPs be enrolled under section 1866(j) of the Act, have in effect a certification by SAMHSA for such a program, and be accredited by an accrediting body approved by SAMHSA. One commenter stated that these policies represent only the start of an ongoing effort to address the opioid epidemic.

Response: We appreciate the support for the proposed definition of OTPs. We understand the importance of combating the opioid epidemic and intend to monitor the implementation of this new Medicare benefit and may propose further refinements in future rulemaking. After consideration of the comments received, we are finalizing our proposed definition of ''opioid treatment program'' at § 410.67(b).

Comment: Commenters supported the proposed Medicare requirements for OTPs, including the requirement that they have in effect a provider agreement with the Secretary. One commenter welcomed CMS' reminder to providers that being a Medicare provider carries with it a limit on charges to beneficiaries, and stated that in addition to the proposal for zero cost sharing for OTP services, this policy would help to protect beneficiary access to care and economic security.

Response: We appreciate the support for the proposal to require OTPs to enter into a provider agreement and are finalizing this requirement at § 410.67(c), along with § 424.67(b). Additionally, we reiterate that as indicated in the Health Insurance Benefit Agreement (Form CMS–1561),[36] the provider agrees to conform to the provisions of section 1866 of the Social Security Act and the applicable provisions in Title 42 Code of Federal Regulations (CFR), which in part establish the requirement that a provider must accept assignment of Medicare payment.

Comment: Many commenters supported CMS' view that the comprehensive OTP standards for certification of OTPs established by SAMHSA address the same topics as would be addressed by CMS conditions of participation, and that the detailed process established by SAMHSA for selecting and overseeing its accreditation organizations is similar to the accrediting organization oversight process that would typically be established by CMS. Furthermore, commenters agreed with CMS' conclusion that the existing SAMHSA certification and accreditation requirements are both appropriate and sufficient to ensure the health and safety of individuals receiving services from OTPs, as well as the effective and efficient furnishing of such services. Commenters also noted the regulations established by the DEA and the regulations established by states for licensure purposes as additional assurances of patient health and safety. The commenters agreed that creating additional conditions at this time for participation in Medicare by OTPs could create unnecessary regulatory duplication and could be potentially burdensome for OTPs. Thus, the commenters supported the proposal to accept the existing SAMHSA requirements for certification and accreditation as the health and safety standards that must be met in order for an OTP to participate in Medicare.

Response: We are finalizing our proposal to adopt the existing SAMHSA requirements for certification and accreditation as the health and safety standards that must be met in order for an OTP to participate in Medicare. This approach will avoid unnecessary regulatory duplication while assuring Medicare beneficiary safety at OTPs.

After consideration of the comments, we are finalizing the proposed definition of ''opioid treatment program'' at § 410.67(b). We are also finalizing the proposed Medicare requirements for OTPs at § 410.67(c). Specifically, in order for an OTP to participate and receive payment under the Medicare program, the OTP must be enrolled under section 1866(j) of the Act, have in effect certification by SAMHSA, and be accredited by an accrediting body approved by SAMHSA. Additionally, we are finalizing our proposal that an OTP must have a provider agreement as required by section 1866(a) of the Act.

3. Bundled Payments for OUD Treatment Services

Section 1834(w) of the Act, added by section 2005 of the SUPPORT Act, directs the Secretary to pay to the OTP an amount that is equal to 100 percent of a bundled payment for OUD treatment services that are furnished by the OTP to an individual during an episode of care. We proposed to establish bundled payments for OUD treatment services which, as discussed above, would include the medications approved by the FDA under section 505 of the FFDCA for use in the treatment of OUD; the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing. In calculating the bundled payments, we proposed to apply separate payment methodologies for the drug component (which includes the medications approved by the FDA under section 505 of the FFDCA for use in the treatment of OUD) and the non-drug component (which includes the dispensing and administration of such medications, if applicable; substance use counseling; individual and group therapy; and toxicology testing) of the bundled payments. We proposed to calculate the full bundled payment rate by combining the drug component and the non-drug components. We outlined our proposals for determining the bundled payments for OUD treatment services addressing payment rates for these services under the Medicaid and

[36] *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1561.pdf.*

TRICARE programs, duration of the episode of care for which the bundled payment is made (including partial episodes), methodology for determining bundled payment rates for the drug and non-drug components, site of service, coding and beneficiary cost sharing. We proposed to codify the methodology for determining the bundled payment rates for OUD treatment services at § 410.67(d).

We received a number of public comments on the proposed approach to calculating the full bundled payment rate. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to calculate the full bundled payment rate by combining the drug component and the non-drug components. Another commenter stated that clinical services, such as individual and group counseling, should be billed separately from the medication.

Response: Section 1861(jjj) of the Act defines OUD treatment services to include certain opioid treatment medications furnished by an OTP, as well as other services such as substance use counseling and individual and group therapy. Section 1834(w) of the Act instructs the Secretary to make a bundled payment for the services that are furnished by an OTP to an individual during an episode of care. We do not believe the statute supports unbundling the medications from the other OUD treatment services furnished by OTPs during the same episode of care.

After consideration of the public comments, we are finalizing our proposal to calculate the full bundled payment rate for services furnished by OTPs by combining the drug component and the non-drug components. We are codifying the methodology for determining the bundled payment rates for OUD treatment services at § 410.67(d).

a. Review of Medicaid and TRICARE Programs

Section 1834(w)(2) of the Act, added by section 2005(c) of the SUPPORT Act, provides that in developing the bundled payment rates for OUD treatment services furnished by OTPs, the Secretary may consider payment rates paid to the OTPs for comparable services under the state plans under title XIX of the Act (Medicaid) or under the TRICARE program under chapter 55 of title 10 of the United States Code (U.S.C.). The payments for comparable services under TRICARE and Medicaid programs are discussed below. In the proposed rule, we acknowledged that many private payers cover services furnished by OTPs, and welcomed comment on the scope of private payer OTP coverage and the payment rates private payers have established for OTPs furnishing comparable OUD treatment services. We also indicated that we might consider this information as part of the development of the final bundled payment rates for OUD treatment services furnished by OTPs.

(1) TRICARE

In the ''TRICARE: Mental Health and Substance Use Disorder Treatment'' final rule, which appeared in the September 2, 2016 **Federal Register** (81 FR 61068) (hereinafter referred to as the 2016 TRICARE final rule), the Department of Defense (DOD) finalized its methodology for determining payments for services furnished to TRICARE beneficiaries by an OTP in the regulations at 32 CFR 199.14(a)(2)(ix). The payments are also described in Chapter 7, Section 5 and Chapter 1, Section 15 of the TRICARE Reimbursement Manual 6010.61–M, April 1, 2015. As discussed in the 2016 TRICARE final rule, a number of commenters indicated that they believed the rates established by DOD are near market rates and acceptable (81 FR 61079).

In the 2016 TRICARE final rule, DOD established separate payment methodologies for treatment in OTPs based on the particular medication being administered. DOD finalized a weekly all-inclusive per diem rate for OTPs when furnishing methadone for MAT. Under 32 CFR 199.14(a)(2)(ix)(A)(3)(i), this weekly rate includes the cost of the drug and the cost of related non-drug services (that is, the costs related to intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and supportive services), hereafter referred as the non-drug services. In the proposed rule (84 FR 40524), we noted that the services included in the TRICARE weekly bundle are generally comparable to the definition of OUD treatment services in section 2005 of the SUPPORT Act. The weekly all-inclusive per diem rate for these services was determined based on preliminary review of industry billing practices (which included Medicaid and other third-party payers) for the dispensing of methadone, including an estimated daily drug cost of $3 and a daily estimated cost of $15 for the non-drug services. These daily costs were converted to an estimated weekly per diem rate of $126 ($18 per day × 7 days) in the 2016 TRICARE final rule. Under 32 CFR 199.14(a)(2)(iv)(C)(2), this rate is updated annually by the Medicare hospital inpatient prospective payment system (IPPS) update factor. The 2019 TRICARE weekly per diem rate for methadone treatment in an OTP is $133.15.[37] Beneficiary cost-sharing consists of a flat copayment that may be applied to this weekly rate.

DOD also established payment rates for other medications used for MAT (buprenorphine and extended-release injectable naltrexone) to allow OTPs to bill for the full range of medications available. Under 32 CFR 199.14(a)(2)(ix)(A)(3)(ii), DOD established a fee-for-service (FFS) payment methodology for buprenorphine and extended-release injectable naltrexone because they are more likely to be prescribed and administered in an office-based treatment setting but are still available for treatment furnished in an OTP. DOD stated in the 2016 TRICARE final rule (81 FR 61080) that treatment with buprenorphine and naltrexone is more variable in dosage and frequency than with methadone. Therefore, TRICARE pays for these medications and the accompanying non-drug services separately on a FFS basis. Buprenorphine is paid based on 95 percent of average wholesale price (AWP) and the non-drug component is paid on a per visit basis at an estimated cost of $22.50 per visit. Extended-release injectable naltrexone is paid at the average sales price (ASP) plus a drug administration fee while the non-drug services are also paid at an estimated per visit cost of $22.50. DOD also reserved discretion to establish the payment methodology for new drugs and biologicals that may become available for the treatment of SUDs in OTPs.

DOD instructed that OTPs use the ''Alcohol and/or other drug use services, not otherwise specified'' H-code for billing the non-drug services when buprenorphine or naltrexone is used, and required OTPs to also include both the J-code and the National Drug Code (NDC) for the drug used, as well as the dosage and acquisition cost on the claim form.[38] Drugs listed on Medicare's Part B ASP files are paid using the ASP.[39] Drugs not appearing on the Medicare ASP file are paid at the lesser of billed

[37] *https://health.mil/Military-Health-Topics/Business-Support/Rates-and-Reimbursement/MHSUD-Facility-Rates.*

[38] 81 FR 61080.

[39] *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/C7S5.html; https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/c1s15.html2FM10546.*

charges or 95 percent of the AWP.[40] Using this methodology, TRICARE estimated a daily drug cost of $10 for buprenorphine and a monthly drug cost of $1,129 for extended-release injectable naltrexone.[41]

(2) Medicaid (Title XIX)

States have the flexibility to administer the Medicaid program to meet their own needs within the Medicaid program parameters set forth in federal statute and regulations. All states cover and pay for some form of medications for MAT of OUD under their Medicaid programs. However, as of 2018, only 42 states covered methadone for MAT for OUD under their Medicaid programs.[42] We note that section 1006(b) of the SUPPORT Act amended sections 1902 and 1905 of the Act to require that Medicaid State plans cover all drugs approved under section 505 of the FFDCA to treat OUD, including methadone, and all biological products licensed under section 351 of the Public Health Service Act to treat OUD, beginning October 1, 2020. This requirement sunsets on September 30, 2025.

In reviewing Medicaid payments for OUD treatment services furnished by OTPs in a few states, we found significant variation in the MAT coverage, OUD treatment services, and payment structure among the states. Thus, it is difficult to identify a standardized Medicaid payment amount for OTP services. A number of factors such as the unit of payment, types of services bundled within a payment code, and how MAT services are paid varied among the states. For example, for treatment of OUD using methadone for MAT, most OTPs bill under HCPCS code H0020 (Alcohol and/or drug services; methadone administration and/or service (provision of the drug by a licensed program)) under the Medicaid program; however, the unit of payment varies by state from daily, weekly, or monthly. For example, the unit of payment in California is daily for methadone treatment,[43] while the unit of payment in Maryland for methadone maintenance is weekly,[44] and Vermont uses a monthly unit[45] of payment of these OUD treatment items and services.

For the other MAT drugs, all states cover buprenorphine and the buprenorphine-naloxone medications;[46] however, fewer than 70 percent cover the implanted or extended-release injectable versions of buprenorphine.[47] In addition, all states cover the extended-release injectable naltrexone.[48] We also found that many states pay different rates based on the specific type of drug used for MAT.

Non-drug items and services may be included in a bundled payment with the drug or paid separately, depending on the state, and can include dosing, dispensing and administration of the drug, individual and group counseling, and toxicology testing. In some states, certain services such as assessments, individual and group counseling, and toxicology testing can be billed separately. For example, some states (such as Maryland,[49] Texas,[50] and California[51]) separately reimburse for individual and group counseling services, while other states (such as Vermont[52] and New Mexico[53]) include these services in the OUD bundled payment.

b. Aspects of the Bundle

(1) Duration of Bundle

Section 1834(w)(1) of the Act requires the Secretary to pay an OTP an amount that is equal to 100 percent of the bundled payment for OUD treatment services that are furnished by the OTP to an individual during an episode of care (as defined by the Secretary) beginning on or after January 1, 2020. We proposed that the duration of an episode of care for OUD treatment services would be a week (that is, a contiguous 7-day period that may start on any day of the week). As noted in the proposed rule, this is similar to the structure of the TRICARE bundled payment to OTPs for methadone, which is based on a weekly bundled rate (81 FR 61079), as well as the payments by some state Medicaid programs. Given this similarity to existing coding structures, we stated that we believe a weekly duration for an episode of care would be most familiar to OTPs, and therefore, the least disruptive to adopt. We proposed to define an episode of care at § 410.67(b) as a 1-week (contiguous 7-day) period; however, we also solicited comments on whether we should consider a daily or monthly bundled payment.

We also recognized that patients receiving MAT are often on this treatment regimen for an indefinite amount of time, and therefore, we did not propose any maximum number of weeks during an overall course of treatment for OUD.

We received a number of public comments on the duration of the bundled payment. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to define an episode of care as a 1-week (contiguous 7-day) period, while several commenters stated that a monthly episode of care may be more appropriate in some circumstances, such as during the maintenance phase of treatment, and a few commenters supported daily bundles because that approach is more consistent with the payment structure under their state Medicaid program. Many commenters were supportive of our decision not to propose any maximum number of weeks for a course of treatment for OUD.

Response: While we recognize that the clinical needs of patients may differ depending on their stage of treatment, we are finalizing our proposal to define an episode of care as a 1-week (contiguous 7-day) period. OTPs are generally familiar with weekly episodes and we believe use of a weekly bundle will be less disruptive to the extent that an OTP already has processes in place to bill for weekly episodes. We recognize that patients receiving MAT are often on this treatment regimen for an indefinite amount of time, and therefore, we are not imposing any limit on the maximum number of weeks

[40] *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/C7S5.html; https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/c1s15.html2FM10546.*

[41] 81 FR 61080.

[42] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport_0.pdf.*

[43] *https://www.dhcs.ca.gov/formsandpubs/Documents/MHSUDS%20Information%20Notices/MHSUDS_Information_Notices_2018/MHSUDS_Information_Notice_18_037_SPA_Rates_Exhibit.pdf.*

[44] *https://health.maryland.gov/bhd/Documents/Rebundling%20Initiative%209-6-16.pdf.*

[45] *http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Medicaid%20Rate%20Sheet.pdf.*

[46] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[47] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[48] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[49] *https://health.maryland.gov/bhd/Documents/Rebundling%20Initiative%209-6-16.pdf.*

[50] *http://www.tmhp.com/News_Items/2018/11-Nov/11-16-18%20Substance%20Use%20Disorder%20Benefits%20to%20Change%20for%20Texas%20Medicaid%20January%201,%202019.pdf.*

[51] *https://www.dhcs.ca.gov/formsandpubs/Documents/MHSUDS%20Information%20Notices/MHSUDS_Information_Notices_2018/MHSUDS_Information_Notice_18_037_SPA_Rates_Exhibit.pdf.*

[52] *http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Medicaid%20Rate%20Sheet.pdf.*

[53] *http://www.hsd.state.nm.us/uploads/FileLinks/e7cfb008157f422597cccdc11d2034f0/MAT_Proposed_reimb_MAD_website_pdf.pdf. https://stre.samhsa.gov/system/files/medicaidfinancingmatreport.pdfnm.us/uploads/FileLinks/c78b68d063e04ce5adffe29376ff402e/12_10_MAT_OTC_Clinics_Supp_09062012__2_.pdf.*

during an overall course of treatment for OUD.

After consideration of the public comments, we are finalizing our proposal to define an episode of care as a 1-week (contiguous 7-day) period at § 410.67(b). We are not finalizing any limit on the maximum number of weeks during an overall course of treatment for OUD.

(a) Requirements for an Episode

In the proposed rule (84 FR 40525), we noted that SAMHSA requires OTPs to have a treatment plan for each patient that identifies the frequency with which items and services are to be provided (§ 8.12(f)(4)). We recognized that there is a range of service intensity depending on the severity of a patient's OUD and stage of treatment, and therefore, a ''full weekly bundle'' may consist of a very different frequency of services for a patient in the initial phase of treatment compared to a patient in the maintenance phase of treatment, but that we would still consider the requirements to bill for the full weekly bundle to be met if the patient is receiving the majority of the services identified in their treatment plan at that time. However, for the purposes of valuation, we assumed one substance use counseling session, one individual therapy session, and one group therapy session per week and one toxicology test per month. Given the anticipated changes in service intensity over time based on the individual patient's needs, we explained that we expect that treatment plans would be updated to reflect these changes or noted in the patient's medical record, for example, in a progress note. In cases where the OTP has furnished the majority (51 percent or more) of the services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week, we proposed that it could bill for a full weekly bundle. We proposed to codify the payment methodology for full episodes of care (as well as partial episodes of care and non-drug episodes of care, as discussed below) in § 410.67(d)(2).

Comment: Several commenters stated that the frequency of services listed in the proposed rule for a typical case (we assumed one substance use counseling session, one individual therapy session, and one group therapy session per week and one toxicology test per month) would usually only occur during the initial phase of treatment/stabilization.

Response: We reiterate that we understand that the frequency of services will vary over time, and may be very different for a patient in the initial phase of treatment compared to a patient in the maintenance phase of treatment. We note that while we identified a set of services for purposes of calculating the payment rate for the weekly bundle, it is not a requirement for billing the bundled payment that all of those services be furnished in a given episode of care. Rather, as we discuss in more detail below, we are finalizing a policy under which the threshold to bill for an episode of care will be that at least one service was furnished to the patient during the week that corresponds to the episode of care.

(b) Partial Episode of Care

As we explained in the proposed rule, we understand that there may be instances in which a beneficiary does not receive all of the services expected in a given week due to any number of issues, including, for example, an inpatient hospitalization during which a beneficiary would not be able to go to the OTP or inclement weather that impedes access to transportation. To provide more accurate payment to OTPs in cases where a beneficiary is not able to or chooses not to receive all items and services described in their treatment plan or the OTP is unable to furnish services, for example, in the case of a natural disaster, we proposed to establish separate payment rates for partial episodes that correspond with each of the full weekly bundles. In cases where the OTP has furnished at least one of the items or services (for example, dispensing one day of an oral MAT medication or one counseling session or one toxicology test) but less than 51 percent of the items and services included in OUD treatment services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week, we proposed that it could bill for a partial weekly bundle. In cases in which the beneficiary does not receive a drug during the partial episode, we proposed that the code describing a non-drug partial weekly bundle must be used. For example, the OTP could bill for a partial episode in instances where the OTP is transitioning the beneficiary from one OUD medication to another and therefore the beneficiary is receiving less than a week of one type of medication. In those cases, two partial episodes could be billed, one for each of the medications, or one partial episode and one full episode, if all requirements for billing are met. We noted our intent to monitor this issue and to consider the need to make changes to this policy in future rulemaking to ensure that the billing for partial episodes is not being abused. We proposed to define a partial episode of care in § 410.67(b) and to codify the payment methodology for partial episodes in § 410.67(d). We solicited comments on our proposed approach to full and partial episodes, including the threshold that should be applied to determine when an OTP may bill for the full weekly bundle versus a partial episode. We also solicited comment on the minimum threshold that should be applied to determine when a partial episode could be billed (for example, at least one item or service, or an alternative threshold such as 10 or 25 percent of the items and services included in the OUD treatment services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week). We also solicited comment regarding whether any other payers of OTP services allow for billing of partial bundles and what thresholds they use.

We received public comments on our proposal to create separate coding and payment for partial episodes. The following is a summary of the comments we received and our responses.

Comment: Many commenters noted that determining the threshold for when to bill the partial episode versus the full episode was impractical, stating it would be cumbersome to implement and would require far more frequent updating of the treatment plan than is typical, especially since the frequency of services delivered can vary significantly from week to week. Commenters also requested clarification on how various services would count toward the 51 percent threshold, and urged CMS to eliminate the partial bundled payment to simplify billing and reduce confusion that could lead to billing compliance issues. A few commenters stated that the total number of services associated with a patient's treatment plan is not documented in a way that would facilitate using the proposed threshold for billing for a full bundle, and therefore, it would not be feasible for OTPs to operationalize the proposed approach. Some commenters also noted that operationalizing this approach would require them to obtain additional administrative resources to track the services provided to each patient in relation to their treatment plan in order to determine when the threshold for billing for a full bundle is met. A few commenters stated that applying partial episodes to the TRICARE bundled rate is inconsistent with TRICARE's approach, which already accounts for differences in treatment intensity in a single unified payment rate. Others recommended that

CMS should not apply partial week payments, as the reduced resource costs for some episodes are already reflected in the payment rate for the full week bundle. A few commenters supported the concept of partial episodes, but requested clarification about the billing threshold.

Response: Based on the concerns raised by the commenters, we are not finalizing partial episodes at this time. We understand that many OTPs would need to change their documentation patterns to operationalize the proposed threshold for determining when to bill a full episode versus a partial episode and that having to make such changes in a short amount of time could be burdensome and potentially create barriers to providing care. In the interest of combating the opioid crisis and in the best interest of beneficiaries, our goal is to minimize barriers to OTPs enrolling in Medicare and beginning to furnish services to Medicare beneficiaries. Accordingly, for CY 2020, we are finalizing only the proposal to establish full weekly bundled payments at § 410.67(d)(2). The threshold to bill a full episode will be that at least one service was furnished (from either the drug or non-drug component) to the patient during the week that corresponds to the episode of care. We are finalizing this threshold at § 410.67(d)(3). We note that we will be monitoring for abuse given this lower threshold for billing for full weekly bundled payment. We also note that we remain interested in implementing a payment policy for partial episodes at some point in the future. We would establish the policies to govern partial episodes through notice and comment rulemaking, and we are interested in working with OTPs to explore how such a policy would best be applied.

(c) Non-Drug Episode of Care

In addition to the bundled payments for full and partial episodes of care that are based on the medication administered for treatment (and include both a drug and non-drug component as described in detail below), we proposed to establish a non-drug episode of care to provide a mechanism for OTPs to bill for non-drug services, including substance use counseling, individual and group therapy, and toxicology testing that are rendered during weeks when a medication is not administered, for example, in cases where a patient is being treated with injectable buprenorphine or naltrexone on a monthly basis or has a buprenorphine implant. We proposed to codify this non-drug episode of care at § 410.67(d).

We did not receive any comments on non-drug episodes of care, and are finalizing the policies governing the use of non-drug episodes of care in § 410.67(d)(1)(iii).

(2) Drug and Non-Drug Components

As discussed above, in establishing the bundled payment rates, we proposed to develop separate payment methodologies for the drug component and the non-drug (which includes the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing) components of the bundled payment. Each of these components is discussed in this section.

(a) Drug Component

As discussed previously, the cost of medications used by OTPs to treat OUD varies widely. Creating a single bundled payment rate that does not reflect the type of drug used could result in access issues for beneficiaries who might be best served by treatment using a more expensive medication. As a result, in the proposed rule (84 FR 40526), we stated our belief that the significant variation in the cost of these drugs would need to be reflected adequately in the bundled payment rates for OTP services to avoid impairing access to appropriate care.

Section 1834(w)(2) of the Act states that the Secretary may implement the bundled payment to OTPs though one or more bundles based on a number of factors, including the type of medication provided (such as buprenorphine, methadone, extended-release injectable naltrexone, or a new innovative drug). Accordingly, consistent with the discretion afforded under section 1834(w)(2) of the Act, and after consideration of payment rates paid to OTPs for comparable services by other payers as discussed above, we proposed to base the OTP bundled payment rates, in part, on the type of medication used for treatment. Specifically, we proposed the following categories of bundled payments to reflect those drugs currently approved by the FDA under section 505 of the FFDCA for use in treatment of OUD:

- Methadone (oral).
- Buprenorphine (oral).
- Buprenorphine (injection).
- Buprenorphine (implant).
- Naltrexone (injection).

In addition, we proposed to create a category of bundled payment describing a drug not otherwise specified to be used for new drugs (as discussed further below). We also proposed a non-drug bundled payment to be used when medication is not administered (as discussed further below) noting that we believe creating these categories of bundled payments based on the drug used for treatment would strike a reasonable balance between recognizing the variable costs of these medications and the statutory requirement to make a bundled payment for OTP services. We proposed to codify this policy of establishing the categories of bundled payments based on the type of opioid agonist and antagonist treatment medication in § 410.67(d)(1).

We received public comments related to our proposal to establish categories of OTP bundled payments based on the type of opioid agonist and antagonist treatment medication used during the episode of care. The following is a summary of the comments we received and our responses.

Comment: Several commenters submitted comments concerning our proposal to base the OTP bundled payment rates, in part, on the type of medication (that is, methadone (oral), buprenorphine (oral), buprenorphine (injection), buprenorphine (implant), naltrexone (injection)) used for treatment. A few commenters supported our proposal to use the five medication categories. Another commenter supported the medication categories but cautioned CMS to monitor and evaluate drug pricing and availability to ensure the payments are sufficient to cover the cost of medications. In contrast, another commenter stated that the medications should not be bundled and that the bundles, if used, were too broad. This commenter believed such an approach would inhibit the ability of the health care provider to choose the best treatment for a patient.

Response: Section 1861(jjj)(1) of the Act defines OUD treatment services to include certain opioid treatment medications furnished by an OTP. Section 1834(w) of the Act instructs the Secretary to make a bundled payment for these services. We do not believe the statute supports unbundling the medications from the other OUD treatment services furnished by OTPs. We defined the five medication categories to represent the distinct types of covered OTP medications currently on the market based on primary active ingredient, method of administration, and cost. We believe these categories of bundled payments strike a reasonable balance between recognizing the variable costs of these medications and the statutory requirement to make a bundled payment for OTP services. We discuss our treatment of new drugs below.

Comment: One commenter urged CMS to clarify whether the naltrexone bundled payment category referred to injectable or oral naltrexone.

Response: The naltrexone drug product that is FDA-approved for the treatment of opioid dependence is an extended-release, intramuscular injection.[54] The naltrexone bundled payment category refers to this injectable product.

Comment: A commenter brought to our attention the fact that buprenorphine-only products are both FDA-approved and marketed for the treatment of opioid dependence by generic manufacturers, whereas in the proposed rule, we stated our understanding that all oral buprenorphine products also contained naloxone as an active ingredient. The commenter recommended that we clarify the definition of buprenorphine products to note the inclusion of these products as well.

Response: Upon further inspection, we have identified marketed buprenorphine-only products. We have also reviewed the available pricing for both the buprenorphine-only and the buprenorphine with naloxone products and found them to be similar. We believe that including both types of products in the same drug category for payment purposes would not negatively impact patient access to either of these two versions of buprenorphine. Therefore, we are clarifying that the proposed ''Buprenorphine (oral)'' drug category includes both the buprenorphine-only and buprenorphine-naloxone products that are currently FDA-approved and marketed for the treatment of opioid dependence.

After consideration of the public comments, we are finalizing our proposal to base the OTP bundled payment rates, in part, on the type of medication used for treatment. These categories reflect those drugs currently approved by the FDA under section 505 of the FFDCA for use in treatment of OUD: that is, methadone (oral), buprenorphine (oral), buprenorphine (injection), buprenorphine (implant), naltrexone (injection)). We will codify this policy of establishing the categories of bundled payments based on the type of opioid agonist and antagonist treatment medication in § 410.67(d)(1).

i. New Drugs

We anticipate that there may be new FDA-approved opioid agonist and antagonist treatment medications to treat OUD in the future. In the scenario where an OTP furnishes MAT using a new FDA-approved opioid agonist or antagonist medication for OUD treatment that is not specified in one of our existing codes, we proposed that OTPs would bill for the episode of care using the medication not otherwise specified (NOS) code (HCPCS code G2075). In such cases, we proposed to use the typical or average maintenance dose to determine the drug cost for the new bundle. We also proposed that pricing would be determined based on the relevant pricing methodology (described in section II.G.3. of this final rule) or invoice pricing in the event the information necessary to apply the relevant pricing methodology is not available. For example, in the case of injectable and implantable drugs, which are generally covered and paid for under Medicare Part B, we proposed to use the methodology in section 1847A of the Act (which bases most payments on ASP). For oral medications, which are generally covered and paid for under Medicare Part D, we proposed to use ASP-based payment when we receive manufacturer-submitted ASP data for these drugs. In the event that we do not receive manufacturer-submitted ASP pricing data, we considered several potential pricing mechanisms (discussed further below) to estimate the payment amounts for oral drugs typically paid for under Medicare Part D but that would become OTP drugs paid under Part B when used as part of MAT furnished in an OTP. We did not propose a specific pricing mechanism for the situation in which we do not receive manufacturer-submitted ASP pricing data, but solicited public comment on several potential approaches for estimating the acquisition cost and payment amounts for these drugs. If the information necessary to apply the alternative pricing methodology chosen for the oral drugs is also not available to price the new medication, we proposed to use invoice pricing until either ASP pricing data or the information necessary to apply the chosen alternate pricing methodology becomes available to price the medication. We proposed to codify this approach for determining the amount of the bundled payment for new medications in § 410.67(d)(2). The medication NOS code would be used until we have the opportunity to consider through rulemaking establishing a unique bundled payment for episodes of care during which the new drug is furnished. We solicited comments on this proposed approach to the treatment of new drugs used for MAT in OTPs.

We received public comments on the proposals related to new drugs. The following is a summary of the comments we received and our responses.

Comment: A few commenters generally supported coverage of new FDA-approved medications for OUD. One commenter noted that a flexible approach to innovative therapies to treat OUD is critical to ensure that Medicare beneficiaries have access to all FDA-approved therapies that best meet their needs.

Response: We believe that our proposal to allow providers to bill using a medication NOS code would offer OTPs the flexibility to provide beneficiaries with quick access to new FDA-approved medications for OUD until we have the opportunity to consider through rulemaking establishing a unique bundled payment for episodes of care during which the new drug is furnished.

Therefore, we are finalizing our proposal to allow OTPs to bill for an episode of care using the medication not otherwise specified (NOS) code (HCPCS code G2075) in the scenario where an OTP furnishes MAT using a new FDA-approved opioid agonist or antagonist medication for OUD treatment that is not specified in one of our existing codes. In such cases, the typical or average maintenance dose would be used to determine the drug cost for the new bundle, which contractors would then add to the non-drug component payment amount that corresponds with the relevant payment for drug administration (oral, injectable, or implantable) to determine the total bundled payment for the episode of care. We are also finalizing our proposal that pricing would be determined based on the relevant pricing methodology as described in section II.G.3. of this final rule or through invoice pricing in the event the information necessary to apply the relevant pricing methodology is not available. We are codifying this approach for determining the amount of the bundled payment for episodes of care with new medications in § 410.67(d)(2)(i)(C).

As discussed above, we also solicited comments on how new medications that may be approved by the FDA in the future for use in the treatment of OUD with a novel mechanism of action (for example, not an opioid agonist and/or antagonist), such as medications approved under section 505 of the FFDCA to treat OUD and biological products licensed under section 351 of the Public Health Service Act to treat OUD, should be considered in the

[54] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

context of OUD treatment services provided by OTPs. Additionally, we solicited comments on how such new drugs with a novel mechanism of action should be priced, and specifically whether pricing for these new non-opioid agonist and/or antagonist medications should be determined using the same pricing methodology proposed for new opioid agonist and antagonist treatment medications, described above or whether an alternative pricing methodology should be used.

We did not receive any comments on the pricing of new drugs with a novel mechanism of action. We intend to monitor for the development of such new drugs for the treatment of OUD, and may consider this topic further in future rulemaking.

(b) Non-Drug Component

i. Counseling, Therapy, Toxicology Testing, and Drug Administration

As discussed above, the bundled payment is for OUD treatment services furnished during the episode of care, which we proposed to define as the FDA-approved opioid agonist and antagonist treatment medications, the dispensing and administration of such medications (if applicable), substance use counseling by a professional to the extent authorized under state law to furnish such services, individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under state law), and toxicology testing. The non-drug component of the OUD treatment services includes all items and services furnished during an episode of care except for the medication.

Under the SAMHSA certification standards at § 8.12(f)(5), OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. We note that section 1861(jjj)(1)(C) of the Act, as added by section 2005(b) of the SUPPORT Act defines OUD treatment services as including ''substance use counseling by a professional to the extent authorized under state law to furnish such services.'' Therefore, professionals furnishing therapy or counseling services for OUD treatment must be operating within state law and scope of practice. These professionals could include licensed professional counselors, licensed clinical alcohol and drug counselors, and certified peer specialists that are permitted to furnish this type of therapy or counseling by state law and scope of practice. To the extent that the individuals furnishing therapy or counseling services are not authorized under state law to furnish such services, the therapy or counseling services would not be covered as OUD treatment services.

Additionally, under the SAMHSA certification standards at § 8.12(f)(6), OTPs are required to provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. These drug abuse tests (which are identified as toxicology tests in the definition of OUD treatment services in section 1861(jjj)(1)(E) of the Act) are used for diagnosing, monitoring and evaluating progress in treatment. The testing typically includes tests for opioids and other controlled substances. Urinalysis is primarily used for this testing; however, there are other types of testing such as hair or fluid analysis that could be used. We note that any of these types of toxicology tests would be considered to be OUD treatment services and would be included in the bundled payment for services furnished by an OTP.

The non-drug component of the bundle also includes the cost of drug dispensing and/or administration, as applicable. Additional details regarding our proposed approach for pricing this aspect of the non-drug component of the bundle are included in our discussion of payment rates later in this section. We did not receive comments on our proposal to include counseling, therapy, toxicology testing, and drug administration in the non-drug component of the bundle.

ii. Other Services

As discussed in the CY 2020 PFS proposed rule, we proposed to define OUD treatment services as those items and services that are specifically enumerated in section 1861(jjj)(1) of the Act, including services that are furnished via telecommunications technology, and solicited comment on any other items and services we might consider including as OUD treatment services under the discretion given to the Secretary in subparagraph (F) of that section to determine other appropriate items and services. We noted that if we were to finalize a definition of OUD treatment services that includes any other items or services, such as intake activities or periodic assessments as discussed above, we would consider whether any changes to the payment rates for the bundled payments would be necessary. As discussed above, we received comments that were supportive of creating add-on payment adjustments for intake activities and periodic assessments, and we are finalizing including intake activities and periodic assessment in the definition of OUD treatment services.

(3) Adjustment to Bundled Payment Rate for Additional Counseling or Therapy Services

In addition to the items and services that we proposed to include in the bundles, we recognized that counseling and therapy are important components of MAT and that patients may need to receive counseling and/or therapy more frequently at certain points in their treatment. In developing our policies for the proposed rule, we sought to ensure that patients have access to these needed services. Accordingly, we proposed to adjust the bundled payment rates through the use of an add-on code in order to account for instances in which effective treatment requires additional counseling or group or individual therapy to be furnished for a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan. As noted previously, we understand that there is variability in the frequency of services a patient might receive in a given week depending on the patient's severity and stage of treatment; however, in the proposed rule, we assumed that a typical case might include one substance use counseling session, one individual therapy session, and one group therapy session per week. As we explained in the proposed rule, we understand that the frequency of services will vary among patients and will change over time based on the individual patient's needs. We expect that the patient's treatment plan or the medical record will be updated to reflect when there are changes in the expected frequency of medically-necessary services based on the patient's condition and following such an update, the add-on code should no longer be billed if the frequency of the patient's counseling and/or therapy services is consistent with the treatment plan or medical record. In the case of unexpected or unforeseen circumstances that are time-limited, resolve quickly, and do not lead to updates to the treatment plan, we explained that we expect the medical necessity for billing the add-on code would be documented in the medical record. The proposed add-on code would reflect each additional 30 minutes of counseling or group or individual therapy furnished in a week of MAT, and could be billed in conjunction with the codes describing the full episode of care. For example,

there may be some weeks when a patient has a relapse or unexpected psychosocial stressors arise that warrant additional reasonable and necessary counseling services that were not foreseen at the time that the treatment plan was developed. We acknowledged that an unintended consequence of using the treatment plan to determine when billing of the add-on code would be permissible is a potential incentive for OTPs to document minimal counseling and/or therapy needs for a beneficiary, thereby resulting in increased opportunity for billing the add-on code. We indicated that we expect OTPs will ensure that treatment plans reflect the full scope of services expected to be furnished during an episode of care and will update treatment plans regularly to reflect changes. We noted that we intend to monitor this issue and would consider making changes to this policy through future rulemaking if necessary to ensure that this payment adjustment is not being billed inappropriately. We solicited comments on the add-on code and the threshold for billing. We proposed to codify this adjustment to the bundled payment rate for additional counseling or therapy services in § 410.67(d)(3)(i).

We received several comments on our proposed adjustment to the bundled payment rate for additional counseling or therapy services. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to create an add-on G-code to adjust the bundled payment rate for additional counseling or therapy services furnished. Several commenters stated that the number of therapy and counseling services described in the proposed rule usually only occurs during the initial stages of treatment and a few commenters stated that patients with that level of need in a given week may be referred for more intensive treatment, such as Intensive Outpatient (IOP) treatment. Some commenters noted the variation in payment rates for counseling across various state Medicaid programs and a few commenters suggested that we use HCPCS code G0396 as a reference code in valuing the payment rate for the counseling add-on code.

Response: After consideration of the public comments, we are finalizing our proposal to establish an add-on code to describe an adjustment to the bundled payment when additional counseling or therapy services are furnished. This add-on payment is codified in the regulations at § 410.67(d)(4)(i)(A). The payment rate we are finalizing for this add-on payment is discussed in more detail later in this final rule. This add-on code may be billed when counseling or therapy services are furnished that substantially exceed the amount specified in the patient's individualized treatment plan. OTPs will be required to document the medical necessity for these services in the patient's medical record. Additionally, we note that we understand the frequency with which counseling and therapy services are furnished will vary over time for each individual patient and will often decrease over time as a patient stabilizes. Nevertheless, we believe it is important to acknowledge that some patients will require more intensive counseling and therapy services at certain times during their treatment and to establish a payment methodology under which OTPs may receive payment for furnishing these medically necessary services.

(4) Site of Service (Telecommunications)

In recent years, we have sought to decrease barriers to access to care by furthering policies that expand the use of communication technologies. In the CY 2019 PFS final rule (83 FR 59482), we finalized new separate payments for communication technology-based services, including a virtual check-in and a remote evaluation of pre-recorded patient information. SAMHSA's federal guidelines (*https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf*) for OTPs refer to the CMS guidance on telemedicine and also state that OTPs are advised to proceed with full understanding of requirements established by state or health professional licensing boards. SAMHSA's federal guidelines for OTPs state that exceptional attention needs to be paid to data security and privacy in this evolving field. Telemedicine services should, under no circumstances, expand the scope of practice of a healthcare professional or permit practice in a jurisdiction (the location of the patient) where the provider is not licensed.

We proposed to allow OTPs to furnish the substance use counseling, individual therapy, and group therapy included in the bundle via two-way interactive audio-video communication technology, as clinically appropriate, in order to increase access to care for beneficiaries. We believed this would be an appropriate approach because, as discussed previously, we expected the telehealth services that will be furnished by OTPs will be similar to the Medicare telehealth services furnished under section 1834(m) of the Act, and the use of two-way interactive audio-video communication technology is required for these Medicare telehealth services under § 410.78(a)(3). By allowing use of communication technology in furnishing these services, OTPs in rural communities or federally-designated geographic health professional shortage areas would be able to facilitate treatment through virtual care coming from an urban or other external site; however, we noted that the physicians and other practitioners furnishing these services would be required to comply with all applicable requirements related to professional licensing and scope of practice.

We noted that section 1834(m) of the Act applies only to Medicare telehealth services furnished by a physician or other practitioner. Because OUD treatment services furnished by an OTP are not considered to be services furnished by a physician or other practitioner, we indicated that the restrictions of section 1834(m) of the Act would not apply. Additionally, we noted that counseling or therapy furnished via communication technology as part of OUD treatment services furnished by an OTP must not be separately billed by the practitioner furnishing the counseling or therapy because these services would already be paid through the bundled payment made to the OTP.

We proposed to include language in § 410.67(b) in the definition of OUD treatment services to allow OTPs to use two-way interactive audio-video communication technology, as clinically appropriate, in furnishing substance use counseling and individual and group therapy services, respectively. We solicited comment as to whether the proposal, including the furnishing of these services through communication technology, would be clinically appropriate. We also solicited public comment on other components of the bundle that may be clinically appropriate to be furnished via communication technology, while considering SAMHSA's guidance that OTPs should pay exceptional attention to data security and privacy.

We received public comments on the proposal to include substance use counseling and individual and group therapy services furnished using telecommunications technology in the definition of OUD treatment services. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to allow OTPs to use two-way interactive audio-video

communication technology, as clinically appropriate, in furnishing substance use counseling and individual and group therapy services, respectively. Several commenters noted that allowing the use of communication technology in furnishing these services has the potential to vastly expand OTPs' reach, particularly in underserved areas. A few commenters urged CMS to afford OTPs maximum flexibility in how telemedicine is deployed, such as allowing the provision of such services regardless of whether or not the counselor or patient is physically located at an OTP and noted that several states already support less restrictive telemedicine practices. One commenter recommended that CMS should also allow OTPs to furnish other important medical services to beneficiaries via telecommunications, including: Medication dose assessment and interactions, basic primary care, and HIV and hepatitis C risk reduction. A few commenters requested clarification as to whether a patient participating in individual and/or group counseling could do so from their home or another location of their choosing as opposed to a designated satellite location.

Response: We are finalizing our proposal to allow OTPs to use two-way interactive audio-video communication technology, as clinically appropriate, in furnishing substance use counseling and individual and group therapy services. In response to the requests for clarification regarding where the beneficiary and practitioner can be located at the time the service is furnished, we note that section 2001 of the SUPPORT Act allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. Accordingly, consistent with this policy, we believe it is appropriate to permit beneficiaries to receive substance use counseling and individual group therapy services furnished by an OTP using telecommunications technology in their home or any other telehealth originating site, provided the requirements that apply to telehealth services payable under the PFS after July 1, 2019, are met. In response to commenters who recommended that CMS should allow OTPs to furnish other medical services to beneficiaries via telecommunications, we note that SAMHSA and the DEA have regulations related to OUD services furnished via telecommunications that we would need further time to consider, but we may revisit this recommendation in developing our policies for future rulemaking.

After consideration of the public comments, we are finalizing our proposal to allow OTPs to use two-way interactive audio-video communication technology, as clinically appropriate, in furnishing substance use counseling and individual and group therapy services. We are also finalizing our proposal to include substance use counseling and individual and group therapy services furnished via two-way interactive audio-video communication technology in the definition of opioid use disorder treatment service in § 410.67(b). We note that as OTP services are not PFS services, no originating site facility fee (HCPCS code Q3014) applies to OUD treatment services, and OTPs are not authorized to bill for the originating site facility fee.

(5) Coding

We proposed to adopt a coding structure for OUD treatment services that would vary by the medication administered. To operationalize this approach, we proposed to establish G codes for weekly bundles describing treatment with methadone, buprenorphine oral, buprenorphine injectable, buprenorphine implants (insertion, removal, and insertion/removal), extended-release injectable naltrexone, a non-drug bundle, and one for a medication not otherwise specified. We also proposed to establish partial episode G codes to correspond with each of those bundles, respectively. Additionally, we proposed to create an add-on code to describe additional counseling that is furnished beyond the amount specified in the patient's treatment plan. We also noted that were we to finalize including intake activities and periodic assessments in the definition of OUD treatment services, we welcomed feedback on whether we should consider modifying the payment associated with the bundle or creating add-on codes for services such as the initial physical examination, initial assessments and preparation of a treatment plan, periodic assessments or additional toxicology testing, and if so, what inputs we might consider in pricing such services, such as payment amounts for similar services under the PFS or CLFS. For example, we noted that to price the initial assessment, medical examination, and development of a treatment plan, we could crosswalk to the Medicare payment rate for a level 3 evaluation and management (E/M) visit for a new patient and to price the periodic assessments, we could crosswalk to the Medicare payment rate for a level 3 E/M visit for an established patient. To price additional toxicology testing, we could crosswalk to the Medicare payment for presumptive drug testing, such as that described by CPT code 80305. Additionally, we welcomed feedback on whether we should consider creating codes to describe bundled payments that include only the cost of the drug and drug administration as applicable in order to account for beneficiaries who are receiving interim maintenance treatment (as described previously in this section) or other situations in which the beneficiary is not receiving all of the services described in the full bundles.

Regarding the non-drug bundle, we noted that this code would be billed for services furnished during an episode of care or partial episode of care when a medication is not administered. For example, when a patient receives a buprenorphine injection on a monthly basis, the OTP will only require payment for the medication during the first week of the month when the injection is given, and therefore, would bill the code describing the bundle that includes injectable buprenorphine during the first week of the month and would bill the code describing the non-drug bundle for the remaining weeks in that month for services such as substance use counseling, individual and group therapy, and toxicology testing.

As discussed previously, we proposed that the codes describing the bundled payment for an episode of care or partial episode of care with a medication not otherwise specified should be used when the OTP furnishes MAT with a new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD. OTPs would use these codes until we have the opportunity to propose and finalize a new G code to describe the bundled payment for treatment using that drug and price it accordingly in the next rulemaking cycle. We noted that the code describing the weekly bundle for a medication not otherwise specified should not be used when the drug being administered is not a new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD, and therefore, for which Medicare would not have the authority to make payment since section 1861(jjj)(1)(A) of the Act requires that the medication must be an opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD. Given the program integrity concerns regarding the

potential for misuse of a medication not otherwise specified code, we also welcomed comments as to whether this code was needed.

See Table 18 for a list of the HCPCS codes for the weekly bundles that we are finalizing (G2067–G2075). We proposed that only an entity enrolled with Medicare as an OTP could bill these codes. Additionally, we proposed that OTPs would be limited to billing only these codes describing bundled payments, and may not bill for other codes, such as those paid under the PFS.

We received many comments related to coding and payment for OTP services. The following is a summary of the comments we received and our responses.

Comment: As described previously, many commenters supported the inclusion of intake activities, such as the initial physician examination, initial assessment and preparation of a treatment plan, as well as periodic assessments in the definition of OUD treatment services. Many commenters suggested that we create add-on codes to describe these services, and several commenters specifically suggested that we use CPT codes 99204 and 99214 as reference codes for pricing the intake and periodic assessment add-ons, respectively. A few commenters recommended that CMS work with OTPs and/or SAMHSA to determine whether an add-on for periodic assessments would sufficiently cover the needs of pregnant and postpartum women who seek care at OTPs.

Response: As discussed above, we are finalizing including intake activities and periodic assessment in the definition of OUD treatment services. It is our understanding that these services are furnished much less frequently than the other services included in the weekly bundled payments; therefore, we are creating add-on G-codes to describe these services, which will allow us to make more targeted payments for these services. We note that the add-on code describing intake activities should only be billed for new patients (that is, patients starting treatment at the OTP). We agree with the commenters that the level 4 office/outpatient E/M visits are a good approximation of the services provided at intake and during periodic assessments at OTPs based on the expected acuity of patients with OUD receiving services at OTPs, who are likely to have multiple co-morbidities and present with problems that are of moderate to high severity and require medical decision making of moderate complexity. Therefore, we are pricing the add-on code describing intake activities using CPT code 99204 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family*) as a reference code, which is assigned a CY 2019 non-facility rate of $166.86 under the PFS in addition to accounting for one toxicology test furnished at intake, using CPT code 80305 (*Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service*) as a reference code, which is assigned a rate of $12.60 under the CLFS in CY 2019. Therefore, we summed those two amounts to calculate the total payment rate for the add-on code describing intake activities, which is $179.46. Similarly, we are pricing the add-on code describing periodic assessments using CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family*) as a reference code, which is assigned a CY 2019 non-facility rate of $110.28 under the PFS. The medical services described by these add-on codes could be furnished by a program physician, a primary care physician or an authorized healthcare professional under the supervision of a program physician or qualified personnel such as nurse practitioners and physician assistants. The other assessments, including psychosocial assessments could be furnished by practitioners who are eligible to do so under their state law and scope of licensure. Additionally, we note that the add-on code describing periodic assessments could be billed for each periodic assessment performed for patients that require multiple assessments during an episode of care, such as patients who are pregnant or postpartum. We note that in order to bill for the add-on code, the services would need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record. We also plan to monitor utilization of the periodic assessment add-on code given program integrity concerns about overutilization, and may consider further refinements in future rulemaking.

Comment: Several commenters supported the creation of add-on codes to account for more frequent presumptive testing, including presumptive testing using instrumented chemistry analyzers, and for definitive testing. Several commenters highlighted the differences between presumptive and definitive tests, stating that CPT code 80305 describes a presumptive screen test by Dipstick or Point of Care rapid test cup, and noted that there is a significant difference in the payment rate for this code compared to the codes describing definitive drug testing. Several commenters requested that CMS set a rate that encompasses medically-appropriate testing frequencies, but also addresses the complexity of testing, noting that that the presumptive screening test uses limited technology and should not be relied upon by clinicians for providing true actionable and reliable information and stated that a bundled rate that includes only a crosswalk to a point-of-care rapid test will severely impact patient care. A few commenters noted that most basic drug tests will not detect Fentanyl and that failure to properly identify Fentanyl may place patients' lives at risk, and therefore, recommended that CMS consider referencing the current CLFS rates for codes HCPCS codes G0480–G0483, which describe definitive drug testing. A few commenters noted that point of care immunoassay testing is rarely able to detect methadone or buprenorphine and can never detect naltrexone and, if methadone or buprenorphine is detected, the immunoassay is unable to determine whether the patient is compliant or is adulterating the urine sample. In contrast, definitive testing is appropriate for detecting all of the drugs used for MAT therapy.

Response: We find the commenters' arguments that both higher level presumptive tests and definitive tests

can be clinically appropriate in the treatment of OUD to be compelling. Further, we want to avoid creating financial disincentives that would prevent OTPs from furnishing medically-necessary care. Accordingly, we are building into the bundled payments both presumptive and definitive testing. We understand from commenters that while SAMHSA requires at least 8 toxicology screenings per year per patient, toxicology screening is frequently done more often, including up to weekly in new patients and that this is most frequently presumptive testing, but in more rare circumstances definitive testing is also performed. Thus, in consideration of what we believe might be an average case, we are assuming that beneficiaries will receive an average of two presumptive tests and one definitive test per month.

We priced the presumptive test based on the CLFS rate for CPT code 80305, which is $12.60, and then prorated that amount by dividing that rate by 2 to reflect the presumption that this type of testing would be furnished only twice a month. We priced the definitive test based on the CLFS rate for HCPCS code G0480, which is $114.43 and then prorated that amount by dividing that rate by 4 to reflect our presumption that this type of testing would be furnished once a month. Additionally, we note that we interpret the statute to require that all toxicology testing furnished by the OTP must be included in the bundled payment or adjustments to the bundled payment and could not be billed separately under the CLFS. We have elected to build the payment for these tests into the weekly bundled rates, rather than creating add-on codes, in order to avoid creating an incentive to furnish testing more frequently than needed. However, as OTPs begin to bill Medicare, if we find that there is an issue with beneficiaries receiving access to medically-necessary definitive testing, we may consider making changes to how these tests are paid through future rulemaking.

Comment: Several commenters stated that OTPs often provide case management and/or care management services and requested that CMS consider reimbursing for these services either as part of the standard bundle or as an adjustment to the bundled payment, as applicable. A few commenters stated that OTPs serve as a fixed point of responsibility in the provision of whole person-centered care and improving health outcomes through collaborative arrangements with health care providers outside of the OTP and that the goal of care management is to reduce health care costs, specifically preventable hospital admissions, readmissions, and avoidable emergency room visits. The commenters also stated that OTP staff also help patients with accessing food benefits, housing, and employment searches, which are critical components for sustained recovery, as part of case management.

Response: We appreciate the feedback and note that we would like to work with OTPs to better understand how these services are furnished in the OTP setting and, as noted previously, we are interested in continued feedback and data on the specific items and services, including their frequency, furnished to beneficiaries by an OTP. We may consider making payment for case management/care management activities in future rulemaking.

We note that the definition of OUD treatment services described in this final rule would need to be revised in future rulemaking to include any such additional items and services.

Comment: A few commenters requested that CMS clarify whether the proposed billing codes could be used when a patient is undergoing detoxification in an OTP and some commenters requested a separate code describing a bundled payment for the costs associated with medications for medically-supervised management of opioid withdrawal, as well as counseling and toxicology testing. One commenter requested guidance to clarify how OTPs could bill for a ''naloxone challenge test'' prior to initiation of treatment with Vivitrol (naltrexone for extended-release injectable suspension).

Response: We note that there is no specified dosage required for billing the bundled payments, so if a patient is tapering off methadone or buprenorphine while undergoing detoxification, the bundled payments describing those drugs may be used if the requirements for billing are satisfied and the non-drug bundle could be billed during any time that the patient is not being dispensed or administered a covered OUD treatment medication. We may consider for future rulemaking whether additional coding or payment changes are needed with respect to detoxification or the provision of naloxone.

Comment: Several commenters requested clarification related to how take-home dosages of medication should be billed. A few commenters noted that the proposed definition of a partial episode does not account for patients who have earned take-home dose privileges and as a result may only attend the OTP once or twice in a month.

Response: We agree with the commenters that additional coding is required to accurately account for the costs associated with providing a patient with take-home doses of medication. Accordingly, we are finalizing two codes to describe adjustments to the bundled payments, one for take-home supplies of methadone, which describes up to 7 additional days of medication, and can be billed along with the respective weekly bundled payment in units of up to 3 (for a total of up to a one month supply), and one for take-home supplies of oral buprenorphine, which also describes up to 7 additional days of medication and can be billed along with the base bundle in units of up to 3 (for a total of up to a 1 month supply). We note that SAMHSA allows a maximum take-home supply of one month of medication; therefore, we do not expect the add-on codes describing take-home doses of methadone and oral buprenorphine to be billed any more than 3 times in one month (in addition to the weekly bundled payment). We also note that the add-on code for take-home doses of methadone can only be used with the methadone weekly episode of care code (HCPCS code G2067). Similarly, the add-on code for take-home doses of oral buprenorphine can only be used with the oral buprenorphine weekly episode of care code (HCPCS code G2068). We are pricing the add-on code describing take-home supplies of methadone, HCPCS code G2078, based on the payment rate for the drug component for the weekly bundle describing treatment with methadone ($35.28) and we are pricing the add-on code describing take home supplies of buprenorphine, HCPCS code G2079, based on the payment rate for the drug component for the weekly bundle describing treatment with oral buprenorphine ($86.26).

Comment: Several commenters requested clarification related to how the bundled payment codes should be billed in a variety of situations. A few commenters specifically requested clarification on how ''guest dosing'' should be billed and others inquired as to whether prior authorization would be required.

Response: In response to comments seeking clarification about the threshold to bill the partial vs. the full episodes, as noted above, we are finalizing only full episodes at this time and will consider partial episodes for future rulemaking. Additionally, as noted above, we are finalizing a number of add-on G codes to describe adjustments

to the bundle. Specifically, we are creating add-on codes for intake activities, periodic assessments, take-home supplies of methadone, take home supplies of oral buprenorphine, and additional counseling furnished. We note that some of the bundled payment codes describe a drug that is typically only administered once per month, such as the injectable drugs, or once in a 6-month period, in the case of the buprenorphine implants. In those cases, the code describing the bundled payment that includes the cost of the drug would be billed during the week that the drug is administered, and if at least once service is furnished in a subsequent week, the non-drug bundle would be billed. For example, in the case of a patient receiving injectable buprenorphine, we would expect that HCPCS code G2069 would be billed for the week during which the injection was administered and that HCPCS code G2074, which describes a bundle not including the drug, would be billed during any subsequent weeks that at least one non-drug service is furnished until the injection is administered again, at which time HCPCS code G2069 would be billed again for that week. We note that as HCPCS codes G2067–G2075 cover episodes of care of 7 contiguous days, we will not permit an OTP to bill any of these codes for the same beneficiary more than once per 7 contiguous day period. Additionally, consistent with FDA labelling, we do not generally expect the codes describing bundled payments including the injectable drugs (HCPCS codes G2069 and G2073) to be furnished more than once every 4 weeks. Similarly, consistent with FDA labelling, we do not generally expect the codes describing bundled payments including insertion of the buprenorphine implants (HCPCS codes G2070 and G2072) to be furnished more than once every 6 months.

However, we do understand there are limited clinical scenarios when a beneficiary may be appropriately furnished OUD treatment services at more than one OTP within a 7 contiguous day period, such as for guest dosing or when a beneficiary transfers care between OTPs. We note that in these limited circumstances, each of the involved OTPs may bill the appropriate HCPCS codes that reflect the services furnished to the beneficiary. We expect that both OTPs involved would provide sufficient documentation in the patient's medical record to reflect the clinical situation and services provided. We will be monitoring the claims data to ensure that this flexibility is not being abused. Additionally, in instances in which a patient is switching from one drug to another, the OTP should only bill for one code describing a weekly bundled payment for that week and should determine which code to bill based on which drug was furnished for the majority of the week. In response to commenters who requested clarification regarding prior authorization, we note that we did not propose, and are not finalizing any prior authorization requirements for services furnished in OTPs, as our goal is not to restrict access to necessary care.

The codes and long descriptors for the OTP bundled services and add-on services we are finalizing are:

- HCPCS code G2067: *Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code G2068: *Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code G2069: *Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code G2070: *Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code G2071: *Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code G2072: *Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code G2073: *Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code G2074: *Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code G2075: *Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code G2076: *Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho-social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.*
- HCPCS code G2077: *Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.*
- HCPCS code G2078: *Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment*

Program); List separately in addition to code for primary procedure.

- HCPCS code G2079: *Take-home supply of buprenorphine (oral); up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.*
- HCPCS code G2080: *Each additional 30 minutes of counseling or group or individual therapy in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.*

Finally, we proposed that only an entity enrolled with Medicare as an OTP could bill these codes. Additionally, we proposed that OTPs would be limited to billing only these codes describing bundled payments, and may not bill for other codes, such as those paid under the PFS. We did not receive comments on these proposals, and are finalizing both these proposals.

(6) Payment Rates

We proposed that the codes describing the OTP bundled services (HCPCS codes G2067–G2075) would be assigned flat dollar payment amounts, as listed in Table 18. As discussed previously, section 2005 of the SUPPORT Act amended the definition of ''medical and other health services'' in section 1861(s) of the Act to provide for coverage of OUD treatment services furnished by an OTP and also added a new section 1834(w) to the Act and amended section 1833(a)(1) of the Act to establish a bundled payment to OTPs for OUD treatment services furnished during an episode of care beginning on or after January 1, 2020. Therefore, OUD treatment services and the payments for such services are wholly separate from physicians' services, as defined under section 1848(j)(3) of the Act, and for which payment is made under section 1848 of the Act. Because OUD treatment services are not considered physicians' services and are paid outside the PFS, we indicated that they would not be priced using relative value units (RVUs).

Consistent with section 1834(w) of the Act, which requires the Secretary to make a bundled payment for OUD treatment services furnished by OTPs, we proposed to build the payment rates for OUD treatment services by combining the cost of the drug and the non-drug components (as applicable) into a single bundled payment as described in more detail below.

(a) Drug Component

As part of determining a payment rate for the proposed bundles for OUD treatment services, a dosage of the applicable medication must be selected in order to calculate the costs of the drug component of the bundle. We proposed to use the typical or average maintenance dose to determine the drug costs for each of the bundles. As dosing for some, but not all, of these drugs varies considerably, this approach attempts to strike an appropriate balance between high- and low-dose drug regimens in the context of a bundled payment. Specifically, we proposed to calculate payment rates using a 100 mg daily dose for methadone, a 10 mg daily dose for oral buprenorphine, a 100 mg monthly dose for the extended-release buprenorphine injection, four rods each containing 74.2 mg of buprenorphine for the 6-month buprenorphine implant, and a 380 mg monthly dose for extended-release injectable naltrexone. We solicited public comments on our proposal to use the typical maintenance dose in order to calculate the drug component of the bundled payment rate for each of the proposed codes. We also solicited comment on the specific typical maintenance dosage level that we have identified for each drug, and a process for identifying the typical maintenance dose for new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA when such medications are billed using the medication NOS code, such as using the FDA-approved prescribing information or a review of the published, preferably peer-reviewed, literature. We noted that the bundled payment rates were intended to be comprehensive with respect to the drugs provided; therefore, we did not intend to include any other amounts related to drugs, other than for administration, as discussed below. This means, for example, that we would not pay for drug wastage, which we did not anticipate to be significant in the OTP setting.

We received several comments on our proposal to use typical maintenance dosage levels to calculate payment rates.

Comment: One commenter expressed concern over the proposal to use average maintenance doses to determine the drug cost component of the bundled payment. This commenter noted that TRICARE explicitly rejected this approach for buprenorphine and naltrexone due to significant variation in the dosage and frequency of administration for these drugs; and, instead, suggested an alternative methodology that would more appropriately account for variations in the clinical needs of patients.

Response: While the TRICARE payment rates for OTP services were considered in determining the Medicare payment for OTP services, we note that section 1834(w)(2) of the Act expressly directs the Secretary to implement the Medicare OTP benefit using one or more payment bundles. We recognize that there may be some variation in the dosage and frequency of administration of these medications. Some beneficiaries may receive a larger than average dose, while other beneficiaries will receive a smaller than average dose; but payment based on the typical dose means that, across the Medicare beneficiaries served by the OTP, the payment amount should be reasonable and represent the average costs incurred in furnishing the drug component of the OUD treatment services. We believe the proposal to use the typical maintenance dosages is a reasonable approach to address the variable dosing of these medications within the statutory direction to implement this payment through one or more bundles.

Comment: Most commenters agreed that the proposed 100 mg daily dose for methadone was reasonable. A couple of commenters also agreed with the proposed typical maintenance dosages of four rods each containing 74.2 mg of buprenorphine for the 6-month buprenorphine implant and a 380 mg monthly dose for extended-release injectable naltrexone. However, several commenters stated that the proposed typical maintenance dosage for oral buprenorphine of 10 mg is too low. A few commenters suggested that there is evidence indicating that higher doses of buprenorphine are associated with better treatment retention. Other commenters stated that OTP patients respond better to a higher dosing level of oral buprenorphine, in part, because they tend to have a longer history of opioid abuse. Commenters suggested potential alternative dosages ranging from 12–20 mg. Several commenters suggested setting the typical maintenance dosage for oral buprenorphine at 16 mg per day. One commenter noted this dosage is supported by SAMHSA's Treatment Improvement Protocol (TIP) 63 (located at *https://store.samhsa.gov/system/files/sma18–5063fulldoc.pdf*). In addition, while a few commenters stated that the 100 mg monthly dose for the extended-release buprenorphine injection was the appropriate maintenance dose, some commenters noted it would not adequately account for the first 2 months of treatment at the higher dose of 300 mg per month. Another commenter stated that there was

evidence indicating certain patients would require longer treatment with the higher dose of the extended-release buprenorphine injection and that the FDA label instructions allowed consideration of increasing the maintenance dose to 300 mg monthly for patients in which the benefits outweigh the risk. One commenter stated that CMS would need to better define how the average maintenance dose was calculated in order to allow for comment on the methodology.

Response: We disagree with the commenter who stated that there was insufficient detail provided in the proposed rule in order to comment on the proposed average maintenance doses. As we described in the proposed rule, we identified the typical maintenance dose for each medication using the FDA-approved prescribing information or through a review of the published, preferably peer-reviewed, literature. We also included a reference in the proposed rule to each of the sources used to identify the typical maintenance doses.

We note that, as the HCPCS codes for the extended-release buprenorphine injection (that is, Q9991: Buprenorphine XR 100 mg or less and Q9992: Buprenorphine XR over 100 mg) have the same payment rate; therefore, we do not believe that it is necessary to establish a second typical maintenance dose to calculate the payment rate for this drug. However, we agree that the typical maintenance dosage for oral buprenorphine should be set higher than the proposed 10 mg. The range offered by commenters was between 12 mg and 20 mg, with a 16 mg per day dose receiving the most support. We also note that SAMHSA's TIP 63 and the FDA labeling support a target dosage of 16 mg for maintenance treatment.[55]

After consideration of the public comments, we are finalizing our proposal to use the typical maintenance dosages to calculate payment rates for the drug component of the weekly bundles (that is, a 100 mg daily dose for methadone, a 100 mg monthly dose for the extended-release buprenorphine injection, four rods each containing 74.2 mg of buprenorphine for the 6-month buprenorphine implant, and a 380 mg monthly dose for extended-release injectable naltrexone) except that the payment rate for the drug component of the oral buprenorphine bundle will be calculated using a typical maintenance dose of 16 mg daily, rather than a 10 mg dose.

[55] See *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022410s038lbl.pdf.*

i. Potential Drug Pricing Data Sources

Payment structures that are closely tailored to the provider's actual acquisition cost reduce the likelihood that a drug will be chosen primarily for a reason that is unrelated to the clinical care of the patient, such as the drug's profit margin for a provider. We proposed to estimate an OTP's costs for the drug component of the bundles based on available data regarding drug costs rather than a provider-specific cost-to-charge ratio or another more direct assessment of facility or industry-specific drug costs. OTPs do not currently report costs associated with their services to the Medicare program, and we did not believe that a cost-to-charge ratio based on such reported information could be available for a significant period of time. Furthermore, we explained that we are unaware of any industry-specific data that may be used to more accurately assess the prices at which OTPs acquire the medications used for OUD treatment. Therefore, we proposed to estimate an OTP's costs for the drugs used in MAT based on other available data sources, rather than applying a cost-to-charge ratio or another more direct assessment of drug acquisition cost; however, we also noted that we intended to continue to explore alternate ways to gather this information. As described in greater detail below, we proposed that the payment amounts for the drug component of the bundles be based on CMS pricing mechanisms currently in place. We solicited comment on other potential data sources for pricing OUD treatment medications either generally or specifically with respect to acquisition by OTPs. In the case of oral drugs that we proposed to include in the OTP bundled payments and for which we do not receive manufacturer-submitted ASP data, we explained that we were considering several potential approaches for determining the payment amounts for the drug component of the bundles. Although we did not propose a specific pricing mechanism, we solicited comments on several different approaches, and stated that we intended to develop a final policy for determining the payment amount for the drug component of the relevant bundles after considering the comments received.

In considering the payment amount for the drug component of each of the bundled payments that include a drug, we began by breaking the drugs into two categories based on their current coverage and payment by Medicare. First, we discussed the injectable and implantable drugs, which are generally covered and paid for under Medicare Part B, and then discussed the oral medications, which are generally covered and paid for under Medicare Part D.[56] Buprenorphine (injection), buprenorphine (implant), and naltrexone (injection) would fall into the former category and methadone and buprenorphine (oral) would fall into the latter category.

ii. Part B Drugs

Part B includes a limited drug benefit that encompasses drugs and biologicals described in section 1861(t) of the Act. Currently, covered Part B drugs fall into three general categories: Drugs furnished incident to a physician's services, drugs administered via a covered item of durable medical equipment, and other drugs specified by statute (generally in section 1861(s)(2) of the Act). Types of providers and suppliers that are paid for all or some of the Medicare-covered Part B drugs that they furnish include physicians, pharmacies, durable medical equipment suppliers, hospital outpatient departments, and end-stage renal disease (ESRD) facilities.

The majority of Part B drug expenditures are for drugs furnished incident to a physician's service. Drugs furnished incident to a physician's service are typically injectable drugs that are administered in a non-facility setting (covered under section 1861(s)(2)(A) of the Act) or in a hospital outpatient setting (covered under section 1861(s)(2)(B) of the Act). The statute (sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act) limits ''incident to'' services to drugs that are not usually self-administered; self-administered drugs, such as orally administered tablets and capsules are not paid for under the ''incident to'' provision. Payment for drugs furnished incident to a physician's service falls under section 1842(o) of the Act. In accordance with section 1842(o)(1)(C) of the Act, ''incident to'' drugs furnished in a non-facility setting are paid under the methodology in section 1847A of the Act. ''Incident to'' drugs furnished in a facility setting also are paid using the methodology in section 1847A of the Act when it has been incorporated under the relevant payment system (for

[56] Because, by law, methadone used in MAT cannot be dispensed by a pharmacy, it is not currently considered a Part D drug when used for MAT. Methadone used for this purpose can be dispensed only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug and can be dispensed by a pharmacy.

example, the Hospital Outpatient Prospective Payment System (OPPS)).[57]

In most cases, payment using the methodology in section 1847A of the Act means payment is determined based on the ASP plus a statutorily-mandated 6 percent add-on. The payment for these drugs does not include costs for administering the drug to the patient (for example, by injection or infusion); payments for these physician and hospital services are made separately, and the payment amounts are determined under the PFS [58] and the OPPS, respectively. The ASP payment amount determined under section 1847A of the Act reflects a volume-weighted ASP for all NDCs that are assigned to a HCPCS code. The ASP is calculated quarterly using manufacturer-submitted data on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act, such as for sales at nominal charge and sales exempt from best price) with manufacturers' rebates, discounts, and price concessions reflected in the manufacturer's determination of ASP.

Although the Part B drug benefit is generally considered to be limited in scope, it includes many categories of drugs and encompasses a variety of care settings and payment methodologies. In addition to the ''incident to'' drugs described above, Part B also covers and pays for certain oral drugs with specific benefit categories defined under section 1861(s) of the Act, including certain oral anti-cancer drugs and certain oral antiemetic drugs. In accordance with section 1842(o)(1) of the Act or through incorporation under the relevant payment system as discussed above, most of these oral Part B drugs are also paid based on the ASP methodology described in section 1847A of the Act.

However, at times Part B drugs are paid based on wholesale acquisition cost (WAC) as authorized under section 1847A(c)(4) of the Act [59] or average manufacturer price (AMP)-based price substitutions as authorized under section 1847A(d) of the Act [60]. Also, in accordance with section 1842(o) of the Act, other payment methodologies may be applied to determine the payment amount for certain Part B drugs, for example, AWP-based payments (using current AWP) are made for influenza, pneumococcal pneumonia, and hepatitis B vaccines.[61] We also use current AWP to make payment under the OPPS for very new drugs without an ASP.[62] Contractors may also make independent payment amount determinations in situations where a national price is not available for physician and other supplier claims and for drugs that are specifically excluded from payment based on section 1847A of the Act (for example, radiopharmaceuticals as noted in section 303(h) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted December 8, 2003). In such cases, pricing may be determined based on compendia or invoices.[63]

While most Part B drugs are paid based on the ASP methodology, MedPAC has noted that the ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs.[64] The ASP payment amount also does not vary based on the price an individual provider or supplier pays to acquire the drug. The statute does not identify a reason for the additional 6 percent add-on above ASP; however, as noted in the MedPAC report (and by sources cited in the report), the add-on is needed to account for handling and overhead costs and/or for additional mark-up in the distribution channels that are not captured in the manufacturer-reported ASP.[65]

We proposed to use the methodology in section 1847A of the Act (which bases most payments on ASP) to set the payment rates for the ''incident to'' drugs. However, we proposed to limit the payment amounts for ''incident to'' drugs to 100 percent of the volume-weighted ASP for a HCPCS code instead of 106 percent of the volume-weighted ASP for a HCPCS code. We explained our belief that limiting the add-on would incentivize the use of the most clinically appropriate drug for a given patient. In addition, we noted that it was our understanding that many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels. We also proposed to use the same version of the quarterly manufacturer-submitted data used for calculating the most recently posted ASP data files in preparing the CY 2020 payment rates for OTPs. We noted that the quarterly ASP Drug Pricing Files include ASP plus 6 percent payment amounts.[66] Accordingly, we adjusted these amounts consistent with our proposal to limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP for a HCPCS code. The proposed payment rates can be found in Table 15 of the CY 2020 PFS proposed rule (84 FR 40537). We proposed to codify the ASP payment methodology for the drug component of weekly bundles that include implantable or injectable medications at § 410.67(d)(2). We solicited public comment on the proposals, as well as on using alternative ASP-based payments to price these drugs, such as a rolling average of the past year's ASP payment rates.

We received several comments on our proposals regarding pricing of Part B drugs. The following is a summary of the comments received and our responses.

Comment: Several commenters expressed concern regarding the proposal to use the methodology in section 1847A of the Act (which bases most payments on ASP) to set the payment rates for the ''incident to'' drugs and to limit the payment amounts to 100 percent of the volume-weighted ASP for a code instead of 106 percent of the volume-weighted ASP for a code. (We note that a similar proposal for setting the payment rates for the oral OTP drugs follows and that several of the comments we received did not specifically reference which group of drugs they were addressing; therefore, we have included a discussion of these comments under both sections.) A few commenters supported the proposal, reasoning that ASP provides a transparent and public benchmark that would allow monitoring for unexpected and unnecessary price changes by manufacturers.

Several other commenters expressed concerns about the proposal to price the Part B injectable and implantable drugs used in the bundle using the ASP without the 6 percent add-on. Commenters noted that the add-on is a necessary part of the payment to account for items such as overhead costs and/or additional mark-ups in the traditional drug distribution channels that are not captured in the manufacturer-reported ASP. A few commenters stated that the 6 percent

[57] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

[58] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

[59] See 75 FR 73465–73466, the section titled Partial Quarter ASP data.

[60] See 77 FR 69140.

[61] Section 1842(o)(1)(A)(iv) of the Act.

[62] 80 FR 70426 and 80 FR 70442–3; Medicare Claims Processing Manual 100–04, Chapter 17, Section 20.1.3.

[63] Medicare Claims Processing Manual 100–04, Chapter 17, Section 20.1.3.

[64] See MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2015, pages 65–72.

[65] Ibid.

[66] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html.*

add-on would allow the OTP to recoup costs associated with rigorous storage and inventory tracking systems required by the DEA. These commenters also stated that the large OTPs, hospitals, and physician systems could skew ASP lower than the prices that smaller or rural OTPs could negotiate on their own. One commenter expressed concerns that OTPs might not be able to afford Part B drugs without the add-on to cover these costs, and suggested a cautious approach to ensure the success of these programs. A few commenters noted that the proposal to price Part B drugs using ASP without the 6 percent add-on would provide a disincentive for an OTP to utilize the most appropriate product for the patient in order to limit their cost of care. Some commenters objected to CMS' statement in the proposed rule that limiting the 6 percent add-on would incentivize the use of the most clinically appropriate drug for a given patient asserting that the 6 percent add-on does not provide an incentive to choose high-cost treatment inappropriately because physicians do not profit from administering Part B drugs under the ASP methodology. Several commenters also questioned CMS' legal authority to limit the payment amount for these drugs to 100 percent of the ASP.

Response: We thank the commenters for their feedback on our proposal to set the payment amounts for ''incident to'' drugs at 100 percent of the volume-weighted ASP. We agree that use of ASP provides a transparent and public benchmark for manufacturers' pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. For this reason, we believe the ASP to be the most market-based approach to set drug prices for the OTP bundled payments.

As noted above, section 1834(w) of the Act grants the Secretary significant discretion to establish bundled payment rates for OUD treatment services. The statute does not dictate the use of any specific methodology, such as the methodology in section 1847A of the Act, in setting the payment rate for the drug component of the bundled payments. Therefore, we do not agree with the comments that indicated CMS has a legal obligation to include the 6 percent add-on when using ASP to determine the payment rate for the drug component of the bundled payments to OTPs for OUD treatment services.

As noted in the proposed rule, we understand that many OTPs purchase medications directly from drug manufacturers, thereby limiting the markup from distribution channels. We received this information during a routine informational industry call with OTP advocates in preparation for drafting the proposed rule. We also note that this fact was not challenged by any of the commenters. Furthermore, we do not believe the record-keeping or storage requirements noted are unique to OTPs. In fact, the selection of drugs purchased by most OTPs is quite limited, which theoretically limits the utility of third-parties, such as wholesalers, and their associated costs and increases the purchase volume for OTPs and accompanying manufacturer discounts. We believe that this situation could lend itself to an OTP drug channel for purchasing at discounted rates either directly or through the use of buying groups as is the standard in the pharmacy industry today. Furthermore, we remain concerned that certain providers will look to differential drug costs to determine which therapies to offer. As a result, we believe that our proposed approach of paying for ''incident to'' drugs based on ASP offers the most appropriate balance between ensuring OTPs receive appropriate reimbursement for their drug acquisition costs, while also preserving the incentive to use the most clinically appropriate drug for the treatment of individual beneficiaries.

After consideration of the public comments, we are finalizing our proposal to use the methodology in section 1847A of the Act (which bases most payments on ASP) to set the payment rates for the ''incident to'' drugs and to limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP for a drug category or code. We are codifying this policy in the regulations at § 410.67(d)(2)(i)(A). However, we continue to be interested in feedback regarding drug acquisition costs for OTP providers, and in particular any drug acquisitions that exceed these rates after factoring in discounts, rebates, etc., and, if necessary, may revisit the payment methodology for ''incident to'' OTP drugs in future rulemaking to ensure that OTPs' drug acquisition costs are appropriately reimbursed.

iii. Oral Drugs

We proposed to use ASP-based payment, which would be determined based on ASP data that have been calculated consistent with the provisions in 42 CFR part 414, subpart 800, to set the payment rates for the oral product categories when we receive manufacturer-submitted ASP data for these drugs. We stated that we believe using the ASP pricing data for oral OTP drugs currently covered under Part D [67] would facilitate the computation of the estimated costs of these drugs. However, we acknowledged that we do not collect ASP pricing information under section 1927(b) of the Act for these drugs. We solicited public comment on whether manufacturers would be willing to submit ASP pricing data for OTP drugs currently covered under Part D on a voluntary basis.

We also proposed to limit the payment amounts for oral drugs to 100 percent of the volume-weighted ASP for a HCPCS code instead of 106 percent of the volume-weighted ASP for that HCPCS code. We explained our belief that limiting the 6 percent add-on would incentivize the use of the most clinically appropriate drug for a given patient. In addition, we explained our understanding that many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels. We proposed to use the same version of the quarterly manufacturer-submitted data used for calculating the most recently posted ASP data files in preparing the CY 2020 payment rates for OTPs. We noted that the quarterly ASP Drug Pricing Files include ASP plus 6 percent payment amounts.[68] Accordingly, we would adjust these amounts consistent with our proposal to limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP for a HCPCS code. The proposed payment rates were provided in Table 15 of the proposed rule. We proposed to codify the ASP payment methodology for the drug component of weekly bundles that include an oral medication at § 410.67(d)(2)(i)(B). We solicited public comment on these proposals, as well as on using alternative ASP-based payments to price these drugs, such as a rolling average of the past year's ASP payment rates.

In the event that we do not receive manufacturer-submitted ASP pricing data, we also considered several potential alternative pricing mechanisms to estimate the payment amounts for oral drugs typically paid for under Medicare Part D but that would become OTP drugs paid under Part B when used as part of MAT in an OTP.

[67] Please note that methadone is not currently considered a Part D drug when used for MAT. Methadone used for this purpose can be dispensed only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug.

[68] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html.*

We did not propose a specific pricing mechanism for these drugs at this time, but solicited public comment on the following potential approaches for estimating the acquisition cost and payment amounts for these drugs and on alternative approaches. We noted that we would consider the comments received in developing our final policy for determining these drug prices.

Approach 1: The Methodology in Section 1847A of the Act

One approach for estimating the cost of the drugs that are currently covered under Part D and for which ASP data are not available would be to use the methodology in section 1847A of the Act. Please see above for a discussion of the payment methodology in section 1847A of the Act. Under the methodology in section 1847A of the Act, when ASP data are not available, this option would price drugs using, for example, WAC or invoice pricing.

Approach 2: Medicare Part D Prescription Drug Plan Finder Data

On January 28, 2005, we issued the ''Medicare Program; Medicare Prescription Drug Benefit'' final rule (70 FR 4194) which implemented the Medicare voluntary prescription drug benefit, as enacted by section 101 of the MMA. Beginning on January 1, 2006, a prescription drug benefit program was available to beneficiaries with much broader drug coverage than was previously provided under Part B to include: Brand-name prescription drugs and biologicals, generic drugs, biosimilars, vaccines, and medical supplies associated with the injection of insulin.[69] This prescription drug benefit is offered to Medicare beneficiaries through Medicare Advantage Drug Plans (MA–PDs) and stand-alone Prescription Drug Plans (PDPs). The prescription drug benefit under Medicare Part D is administered based on the ''negotiated prices'' of covered Part D drugs. Under § 423.100 of the Part D regulations, the negotiated price of a Part D drug equals the amount paid by the Part D sponsor (or its pharmacy benefit manager) to the pharmacy at the point-of-sale for that drug. Typically, these Part D ''negotiated prices'' are based on AWP minus a percentage for brand drugs or either the maximum allowable cost, which is based on proprietary methodologies used to establish the same payment for therapeutically equivalent products marketed by multiple labelers with different AWPs, or the Generic Effective Rate, which guarantees aggregate minimum reimbursement (for example, AWP–85 percent). The negotiated price under Part D also includes a dispensing fee (for example, $1–$2), which is added to the cost of the drug.

Many of the beneficiaries who choose to enroll in Part D drug plans must pay premiums, deductibles, and copayments/co-insurance. The Medicare Prescription Drug Plan Finder is an online tool available at *http://www.medicare.gov.* This web tool allows beneficiaries to make informed choices about enrolling in Part D plans by comparing the plans' benefit packages, premiums, formularies, pharmacies, and pricing data. PDPs and MA–PDs are required to submit this information to CMS for posting on the Medicare Drug Plan Finder. The database structure provides the drug pricing and pharmacy network information necessary to accurately communicate plan information in a comparative format. The Medicare Prescription Drug Plan Finder displays information on pharmacies that are contracted to participate in the sponsors' network as either retail or mail order pharmacies.

Another approach for estimating the cost of the drugs that are currently covered under Part D and for which ASP data are not available would be to use data retrieved from the online Medicare Prescription Drug Plan Finder. For example, the Part D drug prices for each drug used by an OTP as part of MAT could be estimated based on a national average price charged by all Part D plans and their network pharmacies. However, the prices listed in the Medicare Prescription Drug Plan Finder generally reflect the prices that are negotiated by larger buying groups, as larger pharmacies often have significant buying power and smaller pharmacies generally contract with a pharmacy services administrative organization (PSAO). As a result, we indicated that our primary concern with this pricing approach is that such prices may fail to reflect the drug prices that smaller OTP facilities may pay in acquiring these drugs and could therefore disadvantage these facilities. We explained that if we were to select this pricing approach for oral drugs for which ASP data are not available, we would anticipate setting the pricing for these drugs using the most recent Medicare Prescription Drug Plan Finder data available at the drafting of this CY 2020 PFS final rule. We noted that, for the Part B ESRD prospective payment system (PPS) outlier calculation, which provides ESRD facilities with additional payment in situations where the costs for treating patients exceed an established threshold under the ESRD PPS, we chose to adopt the ASP methodology in section 1847A of the Act, and the other pricing methodologies under section 1847A of the Act, as appropriate, when ASP data are not available, to price the renal dialysis drugs and biological products that were or would have been separately billable under Part B prior to implementation of the ESRD PPS,[70] and the national average drug prices based on the Medicare Prescription Drug Plan Finder as the data source for pricing the renal dialysis drugs or biological products that were or would have been separately covered under Part D prior to implementation of the ESRD PPS.[71]

In the proposed rule, we stated that we believe all of the MAT drugs proposed for inclusion in the OTP benefit that are currently covered under Part D have clinical treatment indications beyond MAT such as for the treatment of pain.[72] These drugs will continue to be covered under Part D for these other indications. Buprenorphine will continue to be covered under Part D for MAT as well. Consequently, Part D pricing information should continue to be available for these drugs and could be used in the computation of payment under the approach discussed above.

Because, by law, methadone used in MAT cannot be dispensed by a pharmacy, it is not currently considered a Part D drug when used for MAT. Methadone used for this purpose can be dispensed only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug and can be dispensed by a pharmacy. Accordingly, we also solicited comment on the applicability of Part D payment rates for methadone dispensed by a pharmacy to methadone dispensed by an OTP for MAT.

Approach 3: Wholesale Acquisition Cost (WAC)

Another approach for estimating the cost of the oral drugs that we proposed to include as part of the bundled payments, but for which ASP data are not available, would be to use WAC. Section 1847A(c)(6)(B) of the Act defines WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers in the U.S., not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for

[69] See section 1860D–2(e) of the Act.

[70] 82 FR 50742 through 50745.

[71] 75 FR 49142.

[72] For example, while methadone is not covered by Medicare Part D for MAT, methadone dispensed for pain may be considered a Part D drug.

which the information is available, as reported in wholesale price guides or other publications of drug pricing data. As noted above in the discussion of Part B drugs, WAC is used as the basis for pricing some Part B drugs; for example, it is used when it is less than ASP in the case of single source drugs (section 1847A(b)(4) of the Act) and in cases where ASP is unavailable during the first quarter of sales (section 1847A(c)(4) of the Act).

Because WAC is the manufacturer's list price to wholesalers, we noted that we believe it is more reflective of the price paid by the end user than the AWP. As a result, we believe that this pricing mechanism would be consistent with pricing that currently occurs for drugs that are separately billable under Part B. However, we have concerns about the fact that WAC does not include prompt pay or other discounts, rebates, or reductions in price. We noted that if we were to select this option to estimate the cost of certain drugs, we would develop pricing using the most recent data files available at the time of drafting this CY 2020 PFS final rule.

Approach 4: National Average Drug Acquisition Cost (NADAC)

Another approach for estimating the cost of the oral drugs that we proposed to include as part of the bundled payments, but for which ASP data are not available, would be to use Medicaid's NADAC survey. This survey provides another national drug pricing benchmark. CMS conducts surveys of retail community pharmacy prices, including drug ingredient costs, to develop the NADAC pricing benchmark. The NADAC was designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs and is available for consideration by states to assist with their individual pharmacy payment policies.

State Medicaid agencies reimburse pharmacy providers for prescribed covered outpatient drugs dispensed to Medicaid beneficiaries. The reimbursement formula consists of two parts: (1) Drug ingredient costs; and (2) a professional dispensing fee. In a final rule with comment period titled ''Medicaid Program; Covered Outpatient Drugs,'' which appeared in the February 1, 2016 **Federal Register** (81 FR 5169), we revised the methodology that state Medicaid programs use to determine drug ingredient costs, establishing an Actual Acquisition Cost (AAC) based determination, as opposed to a determination based on estimated acquisition costs (EAC). AAC is defined at 42 CFR 447.502 as the agency's determination of the pharmacy providers' actual prices paid to acquire drugs marketed or sold by specific manufacturers. As explained in the Covered Outpatient Drugs final rule with comment period (81 FR 5175), we believe shifting from an EAC to an AAC based determination of ingredient costs is more consistent with the dictates of section 1902(a)(30)(A) of the Act. In 2010, a working group within the National Association of State Medicaid Directors (NASMD) recommended the establishment of a single national pricing benchmark based on average drug acquisition costs. Pricing metrics based on actual drug purchase prices provide greater accuracy and transparency in how drug prices are established and are more resistant to manipulation. The NASMD requested that CMS coordinate, develop, and support this benchmark.

Section 1927(f) of the Act provides, in part, that CMS may contract with a vendor to conduct monthly surveys with respect to prices for covered outpatient drugs dispensed by retail community pharmacies. We entered into a contract with Myers & Stauffer, LLC to perform a monthly nationwide retail price survey of retail community pharmacy covered outpatient drug prices (CMS–10241, OMB 0938–1041) and to provide states with weekly updates on pricing files, that is, the NADAC files. The NADAC survey process focuses on drug ingredient costs for retail community pharmacies. The survey collects acquisition costs for covered outpatient drugs purchased by retail pharmacies, which include invoice prices from independent and chain retail community pharmacies. The survey data provide information that CMS uses to assure compliance with federal requirements. In the proposed rule, we explained that we believe NADAC data could be used to set the prices for the oral drugs furnished by OTPs for which ASP data are not available. Survey data on invoice prices provide the closest pricing metric to ASP that we are aware of. However, we also noted that similar to the other available pricing metrics, we have concerns about the applicability of retail pharmacy prices to the acquisition costs available to OTPs since we have no evidence to suggest that these entities would be able to acquire drugs at a similar price point. We noted that if we were to select this option to estimate the cost of certain drugs, we would develop pricing using the most recent data files available at the time of drafting this CY 2020 PFS final rule.

Alternative Methadone Pricing: TRICARE

We also considered an approach for estimating the cost of methadone using the amount calculated by TRICARE. As discussed above in this section of this final rule, the TRICARE rates for medications used in OTPs to treat OUD are spelled out in the 2016 TRICARE final rule (81 FR 61068); in the regulations at 32 CFR 199.14(a)(2)(ix); and in Chapter 7, Section 5 and Chapter 1, Section 15 of the TRICARE Reimbursement Manual 6010.61–M, April 1, 2015.

In the 2016 TRICARE final rule, DOD established separate payment methodologies for OTPs based on the particular medication being administered for treatment.[73] Based on TRICARE's review of industry billing practices, the initial weekly bundled rate for administration of methadone included a daily drug cost of $3, which is subject to an update factor.[74]

We noted that this option would only be applicable for methadone because TRICARE has developed a FFS payment methodology for buprenorphine and naltrexone.[75] In the 2016 TRICARE final rule, the DOD stated that the payments for buprenorphine and naltrexone are more variable in dosage and frequency for both the drug and non-drug services.[76] Accordingly, TRICARE pays for drugs listed on Medicare's Part B ASP files, such as the injectable and implantable versions of buprenorphine using the ASP; drugs not appearing on the Medicare ASP file, such as oral buprenorphine, are priced at the lesser of billed charges or 95 percent of the AWP.[77]

We stated that we believed that pricing methadone consistent with the TRICARE payment rate could provide a reasonable payment amount for methadone when ASP data are not available. As DOD noted in the 2016 TRICARE final rule, ''a number of commenters indicated that they believed the rates DOD proposed for OTPs' services are near market rates and are acceptable.'' [78]

We proposed to codify this proposal to apply an alternative approach for determining the payment rate for oral drugs only if ASP data are not available in § 410.67(d)(2)(i)(B). We solicited

[73] 81 FR 61079.

[74] 81 FR 61079.

[75] 81 FR 61080.

[76] 81 FR 61080.

[77] *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/C7S5.html; https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/c1s15.html2FM10546.*

[78] 81 FR 61080.

public comment on the potential alternative approaches for estimating the cost of oral drugs that we proposed to include as part of the bundled payments but for which ASP data are not available, including any other alternate sources of data to estimate the cost of these oral MAT drugs. Payment rates based on these different options were set forth in Table 14 of the proposed rule. We stated that we would consider the comments received on these different approaches when deciding on the approach that we would use to determine the payment rates for oral drugs in the CY 2020 PFS final rule. We also solicited public comment on any other potential data sources for estimating the provider acquisition costs of OTP drugs currently paid under either Part B or Part D.

We received several comments on our proposals regarding pricing of oral drugs. The following is a summary of the comments received and our responses.

Comment: Several commenters submitted comments on the proposal to use ASP-based payment to set the payment rates for the oral product categories when we receive manufacturer-submitted ASP data for these drugs and to limit the payment amounts for oral drugs to 100 percent of the volume-weighted ASP instead of 106 percent of the volume-weighted ASP. (We note that a similar proposal for the injectable and implantable Part B drugs is discussed above and that several of the comments we received did not specifically reference which group of drugs they were concerning; therefore, we have included a discussion of these comments under both sections.) A few commenters supported the proposal, reasoning that ASP provides a transparent and public benchmark that would allow monitoring for unexpected and unnecessary price changes by manufacturers; and a couple of commenters encouraged us to require manufacturers to report these data.

Several other commenters expressed concerns about the proposal to price the oral drugs used in the bundle using the ASP without the 6 percent add-on. Commenters stated that the add-on is a necessary part of the payment to account for things such as overhead costs and/or additional mark-ups in the traditional drug distribution channels that are not captured in the manufacturer-reported ASP. A few commenters stated that the 6 percent add-on would allow the OTP to recoup costs associated with rigorous storage and inventory tracking systems required by the DEA. These commenters also stated that large OTPs, hospitals, and physician systems could skew ASP lower than the prices that smaller or rural OTPs could negotiate on their own. One commenter expressed concerns that OTPs might not be able to afford the oral drugs used in MAT without the add-on to cover these costs, and suggested that the Administration should be overly cautious to ensure success of these programs. Some commenters expressed concerns that this proposal would provide a disincentive for an OTP to utilize the most appropriate product for the patient to limit their cost of care. Several commenters also questioned CMS' legal authority to limit the payment amount for these drugs to 100 percent of the ASP.

Response: We thank the commenters for their feedback on our proposal to use ASP-based payment to set the payment rates for the oral product categories when we receive manufacturer-submitted ASP data for these drugs and to limit the payment amounts for oral drugs to 100 percent of the volume-weighted ASP instead of 106 percent of the volume-weighted ASP. We agree that use of ASP provides a transparent and public benchmark for manufacturers' pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. For this reason, we believe the ASP to be the most market-based approach to set drug prices for the OTP benefit.

As noted above, section 1834(w) of the Act grants the Secretary considerable discretion to establish bundled payment rates for OUD treatment services. The statute does not dictate use of any specific methodology, such as the methodology in section 1847A of the Act, in setting these payments. We used our discretion, granted by the Act, in proposing to modify the methodology in section 1847A of the Act to set payments to OTPs for oral drugs for which ASP data are available. Therefore, we do not agree with the comments that indicated CMS has a legal obligation to include the 6 percent add—when using ASP to determine payments to OTPs for oral drugs.

As noted in the proposed rule, we understand that many OTPs purchase medications directly from drug manufacturers, thereby limiting the markup from distribution channels. We received this information during a routine informational industry call with OTP advocates in preparation for drafting the proposed rule. We also note that this fact was not challenged by any of the commenters. Furthermore, we do not believe the record-keeping or storage requirements noted are unique to OTPs. In fact, the selection of drugs purchased by most OTPs is quite limited, which theoretically limits the utility of third-parties, such as wholesalers, and their associated costs and increases the purchase volume for OTPs and accompanying manufacturer discounts. We believe that this situation could lend itself to an OTP drug channel for purchasing at discounted rates either directly or through the use of buying groups as is the standard in the pharmacy industry today. Furthermore, we remain concerned that certain providers will look to differential drug costs to determine which therapies to offer. As a result, we believe that our proposed approach of paying for oral drugs based on ASP, when available, offers an appropriate balance between ensuring OTPs receive appropriate reimbursement for their drug acquisition costs, while also preserving the incentive to use the most clinically appropriate drug for the treatment of individual beneficiaries.

After consideration of the public comments, we are finalizing our proposal to use ASP-based payment to set the payment rates for the oral drugs and to limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP when it is available. However, we continue to be interested in feedback regarding drug acquisition costs for OTP providers, and in particular any drug acquisitions that exceed these rates after factoring in discounts, rebates, etc., and if necessary, may revisit the payment methodology for oral OTP drugs in future rulemaking to ensure that OTPs' drug acquisition costs are appropriately reimbursed.

Comment: A few commenters submitted comments on the potential pricing mechanisms described in the proposed rule to estimate the payment amounts for oral OTP drugs in the event that we do not receive manufacturer-submitted ASP pricing data. Some commenters supported establishing payments based on current Medicare law and practice, such as the rates provided under Part D, for other oral drugs. Another commenter advised against using methods such as AWP and WAC as these options can be manipulated by the manufacturers. This commenter also noted that NADAC and the Medicare Plan Finder prices may not be relevant to all OTP medications as they are retail-based price measures and OTPs are providers. One commenter suggested use of the methodology in section 1847A of the

Act, which would generally default to WAC-based payment if ASP is not reported. One commenter generally opposed the use of TRICARE rates, while another specifically stated that the current TRICARE payment rate for methadone, as presented in the proposed rule, is fair and should be used as a reference price for Medicare.

Response: We agree with commenters that using current programmatic pricing mechanisms where available is preferable to a pricing methodology that is novel and unproven. As oral buprenorphine used for OUD is currently dispensed by retail pharmacies, we believe that a retail-based pricing method may be most relevant to this drug product and more reflective of actual costs than a list price. As noted above, the NADAC survey collects acquisition costs for covered outpatient drugs purchased by retail pharmacies, which include invoice prices from independent and chain retail community pharmacies. Pricing metrics based on actual drug purchase prices provide greater accuracy and transparency in how drug prices are established and are more resistant to manipulation. As the NADAC survey data on invoice prices provide the closest pricing metric to ASP that we are aware of, we believe, at this time, that NADAC data would be the best pricing benchmark to set the prices for non-methadone oral drugs (that is, currently only the oral buprenorphine products) furnished by OTPs for which ASP data are not available. We further agree that retail pricing benchmarks, such as NADAC and Part D Plan Finder data, may not be particularly relevant for methadone, because methadone is not dispensed by retail pharmacies for this indication and its use for OUD is limited to OTPs. As a result, we believe that use of the TRICARE rate for methadone, when ASP data are not available, is currently the most applicable reference price for Medicare payment of methadone used in the OTP setting.

After consideration of the public comments, we are finalizing our proposal to use ASP-based payment to set the payment rates for the oral product categories when we receive manufacturer-submitted ASP data for these drugs and to limit the payment amounts for oral drugs to 100 percent of the volume-weighted ASP. We have used the same version of the quarterly manufacturer-submitted data used for calculating the most recently posted ASP data files to determine the CY 2020 payment rates for OTPs. When ASP data are not available for the oral drugs used in OTPs, we are finalizing a policy under which we will use the TRICARE rate to set the payment for the drug component of the methadone bundle, and NADAC data to set the payment for the drug component of the oral buprenorphine bundle. Payment rates for these drugs are provided in Table 18. We note that, for purposes of determining payment for CY 2020, we were able to calculate an ASP for methadone using manufacturer reported data. However, we did not receive ASP data from any of the buprenorphine oral manufacturers. Therefore, the drug component of the oral buprenorphine weekly bundle will be priced using NADAC survey data. We are finalizing this payment methodology for the oral drugs at § 410.67(d)(2)(i)(B).

(b) Non-Drug Component

To price the non-drug component of the bundled payments, we proposed to use a crosswalk to the non-drug component of the TRICARE weekly bundled rate for services furnished when a patient is prescribed methadone. As described above, in 2016, TRICARE finalized a weekly bundled rate for administration of methadone that included a daily drug cost of $3, along with a $15 per day cost for non-drug services (that is, the costs related to the intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and supportive services). The daily projected per diem cost ($18/day) was converted to a weekly rate of $126 ($18/day × 7 days) (81 FR 61079). TRICARE updates the weekly bundled methadone rate for OTPs annually using the Medicare update factor used for other mental health care services rendered under TRICARE (that is, the Inpatient Prospective Payment System update factor) (81 FR 61079). The updated amount for CY 2019 is $133.15 (of which $22.19 is the methadone cost and the remainder, $110.96, is for the non-drug services).[79] In the proposed rule, we stated that we believed using the TRICARE weekly bundled rate would be a reasonable approach to setting the payment rate for the non-drug component of the bundled payments to OTPs, particularly given the time constraints in developing a payment methodology prior to the January 1, 2020 effective date of this new Medicare benefit category. The TRICARE rate is an established national payment rate that was established through notice and comment rulemaking. As a result, OTPs and other interested parties had an opportunity to present information regarding the costs of these services. Furthermore, the TRICARE rate describes a generally similar bundle of services to those services that are included in the definition of OUD treatment services in section 1861(jjj)(1) of the Act. We recognized that there are differences in the patient population for TRICARE compared with the Medicare beneficiary population. However, as OTP services have not previously been covered by Medicare, we noted that it is not clear what impact, if any, these differences would have on the cost of the services included in the non-drug component of the bundled payments. We proposed to codify the methodology for determining the payment rate for the non-drug component of the bundled payments using the TRICARE weekly rate for non-drug services at § 410.67(d)(2). As part of the proposal, we noted that we would plan to monitor utilization of non-drug services by Medicare beneficiaries and, if needed, would consider in future rulemaking ways we could tailor the TRICARE payment rate for these non-drug services to the Medicare population, including dually eligible beneficiaries.

Because the TRICARE payment rate for the non-drug services included in its weekly bundled rate for methadone reflects the daily administration of methadone, as part of our proposed approach we indicated that we would adjust the TRICARE payment rate for non-drug services for most of the other bundled payments to more accurately reflect the cost of administering the other drugs used in MAT. For the oral buprenorphine bundled payment, we proposed to retain the same amount as the rate for the methadone bundled payment based on an assumption that this drug is also being dispensed daily. We stated that we understood that patients who have stabilized may be given 7–14 day supplies of oral buprenorphine at a time, but for the purposes of developing the proposed rates, we proposed to value this service to include daily drug dispensing to account for cases where daily drug dispensing is occurring. For the injectable drugs (buprenorphine and naltrexone), we proposed to subtract from the non-drug component, an amount that is comparable to the dispensing fees paid by several state Medicaid programs ($10.50) for a week of daily dispensing of methadone. This adjustment would account for the fact that these injectable drugs are not oral drugs that are dispensed daily; we proposed that we would then instead add the fee that Medicare pays for the

[79] *https://health.mil/Military-Health-Topics/Business-Support/Rates-and-Reimbursement/MHSUD-Facility-Rates.*

administration of an injection (which is currently $16.94 under the CY 2019 non-facility Medicare payment rate for CPT code 96372). We proposed to update the amount of this adjustment annually using the same methodology that we were proposing to use to update the non-drug component of the bundled payments.

Similarly, we proposed that the payment rates for the non-drug component of the codes for the weekly bundled payments for buprenorphine implants would be adjusted to add an amount for insertion and/or removal of the implants based on a direct crosswalk to the non-facility payment rates under the Medicare PFS for the insertion, removal, or insertion and removal of these implants, which describe the physician work, PE, and malpractice costs associated with these procedures, and to remove the costs of daily drug dispensing (determined based on the dispensing fees paid by several state Medicaid programs for a week of daily dispensing of methadone, currently $10.50). For the code describing implant insertion, we proposed that we would use a crosswalk to the rate for HCPCS code G0516 (*Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant*)); for the code describing implant removal, we proposed that we would use a crosswalk to the rate for HCPCS code G0517 *(Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)*); and for the code describing implant insertion and removal, we proposed that we would use a crosswalk to the rate for HCPCS code G0518 (*Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants*)). We note that in the proposed rule, we inadvertently misstated the amounts for HCPCS codes G0516, G0517, and G0518. The correct amounts for HCPCS codes G0516, G0517, and G0518 under the CY 2019 non-facility Medicare payment rate are $246.15, $265.61, and $465.26, respectively.

To determine the payment rates for the code describing a non-drug bundled payment, we proposed to use a crosswalk to the reimbursement rate for the non-drug services included in the TRICARE weekly bundled rate for administration of methadone, adjusted to subtract the cost of methadone dispensing (using an amount that is comparable to the dispensing fees paid by several state Medicaid programs for a week of daily dispensing of methadone, which is currently $10.50).

We proposed that the payment rate for the add-on code for each additional 30 minutes of counseling or group or individual therapy would be based on 30 minutes of substance use counseling and valued based on a crosswalk to the rates set by state Medicaid programs for similar services.

We received a number of public comments on our proposed payment rates for the non-drug component of the bundled payment and the add-on code for additional counseling or therapy services. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that the proposed rate for the non-drug component of the bundled payment was insufficient. A few commenters expressed concern that establishing a Medicare rate that is lower than the rates set by some state Medicaid programs would destabilize the market. Some commenters recommended that the single full week TRICARE payment rate should be the floor used to pay for a basic Medicare OTP benefit assuming a similar level of service and that any additional services, such as extra counseling and/or therapy visits, should be reimbursed outside of the bundle, as CMS proposed for counseling sessions above the basic benefit and stated that if additional services are added to the basic benefit, the bundled payment should increase to reflect the additional services. Some commenters stated that the proposed rate reflects a market rate that is significantly discounted, noting that it is benchmarked on an insurance industry practice rooted in stigma and limited resources and expressed concern that it may inadvertently limit access to care at a time when the opioid overdose epidemic continues to cause significant mortality. Additionally, a few commenters noted that the TRICARE rate reflects the average cost of care for the typical TRICARE patient, but that they believed Medicare patients would generally require more services. A few commenters noted that the only difference between OTPs and office-based OUD treatment is the means of regulation and medication offered, and that therefore, the different settings should not be cause to pay differentially. Some commenters encouraged CMS to adjust the payment rates to account for severity of illness. Several commenters stated that the proposed rate for counseling is too low, which would make it difficult for providers to employ qualified practitioners. Several commenters urged CMS to use a building block methodology, which sums the Medicare payment rates for similar services furnished in the non-facility setting, to calculate the payment rate for the non-drug component.

Response: After consideration of the public comments, we are finalizing a payment rate for the non-drug component that is calculated based on a building block methodology using the Medicare payment rates for similar services furnished in the non-facility setting. We note that we considered a variety of different rates, including TRICARE and Medicaid, and decided ultimately to use Medicare rates for similar services. We appreciate commenters' feedback about the TRICARE rate, including the concern that it reflects an average cost of care for the TRICARE patient population, and note that by finalizing payment rates using the established rates for similar services under Medicare, we believe these rates will be more reflective of the resource costs involved in furnishing services to the Medicare patient population. We also acknowledge that establishing a methodology under which Medicare payments would be less than those made by state Medicaid programs could create unnecessary barriers to access to care. Additionally, we recognize that a differential in payment OUD treatment services furnished by OTPs and OUD treatment furnished in the office setting may set up a disparity that could disadvantage OTPs.

The services that are included in the non-drug component of the weekly bundles are the same services that are included in the TRICARE rate, which are individual therapy, group therapy, substance use counseling, and toxicology testing. Therefore, we believe that a reasonable alternative approach is to finalize payment rates for the non-drug component of the bundled payments for CY 2020 that are determined using a building block methodology under which the payment rate for the same set of non-drug services is based on established rates for similar services under the Medicare PFS (non-facility rates), the Medicare CLFS, and state Medicaid programs.

Specifically, the payment rate we are finalizing for the non-drug component reflects the Medicare payment rates for the following codes as reference codes for the services that are included in the TRICARE rate, (individual therapy, group therapy, substance use counseling, and toxicology testing): CPT code 90832 (*Psychotherapy, 30 minutes with patient*), in CY 2019 is currently assigned a non-facility rate of $68.47 under the PFS; CPT code 90853 (*Group psychotherapy (other than of a multiple-family group)*), which in CY 2019 is assigned a non-facility rate of $27.39

under the PFS; HCPCS code G0396 (*Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes*), which in CY 2019 is assigned a non-facility rate of $30.94 under the PFS when furnished by nonphysician practitioners (NPPs), as we believe this is a more accurate reflection of the practitioner type who would be furnishing substance use counseling in an OTP; CPT code 80305 (*Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service*), which in CY 2019 is assigned a rate of $12.60 under the CLFS, and which we will prorate to account for two tests per month in the base bundled payment; and HCPCS code G0480 *(Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to gc/ms (any type, single or tandem) and lc/ms (any type, single or tandem and excluding immunoassays (e.g., ia, eia, elisa, emit, fpia) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1–7 drug class(es), including metabolite(s) if performed*), which in CY 2019 is assigned a rate of $114.43 under the CLFS, and which we will prorate to account for one test per month in the base bundled payment, as discussed previously. The sum of these amounts is $161.71.

We are also finalizing our proposal to adjust the non-drug component rate to account for different administration and dispensing costs of the drug that is used in the episode of care (either oral, injectable, or implantable). We note that in calculating the proposed rates, the TRICARE weekly bundled rate included administration of oral drugs, which we then adjusted accordingly for the other bundled payments by subtracting the amount for dispensing oral drugs and adding a different amount to account for administration of the injectable and implantable drugs. We are finalizing the rate we proposed for dispensing oral drugs using an approximation of the average dispensing fees under state Medicaid programs, which is $10.50, since there is no Medicare Part B rate for oral MAT drugs. For the injectable drugs (buprenorphine and naltrexone), we proposed to subtract from the non-drug component an amount that is comparable to the dispensing fees paid by several state Medicaid programs ($10.50) for a week of daily dispensing of methadone, and to add the Medicare non-facility rate for administration of an injection. This adjustment was necessary to account for the fact that the TRICARE rate includes oral dispensing fees, whereas these injectable drugs are not oral drugs that are dispensed daily. However, because we are adopting a building block methodology in final rule to determine the payment rate for the non-drug component of the weekly bundles, it is no longer necessary to subtract the oral dispensing fee; however, as we proposed, we will include the Medicare non-facility rate for administration of an injection in our determination of the payment rate for the non-drug component for weekly bundles that include injectable drugs. We are finalizing the rate we proposed for administration of an injection, based on CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*) as a reference code, is $16.94.

For the codes describing the insertion, removal, or insertion and removal of the buprenorphine implants, we proposed to adjust the non-drug component payment rate to remove the cost of daily administration of an oral drug and by adding the Medicare non-facility payment rate for the insertion, removal, or insertion and removal of the implants, respectively. Again, removal of the cost of daily administration of an oral drug is no longer necessary under our building block methodology; but, we are finalizing our proposal to include the rates for the insertion, removal, or insertion and removal of the buprenorphine implants, as applicable. The reference codes, which we proposed and are finalizing are: HCPCS codes G0516 (*Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant)*), which in CY 2019 is assigned a non-facility rate of $246.15. G0517 (*Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)*), which in CY 2019 is assigned a non-facility rate of $265.61 under the PFS, and G0518 (*Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)*), which in CY 2019 is assigned a non-facility rate of $465.26 under the PFS. Under the building block methodology we are adopting in this final rule, the total non-drug component payment for the non-drug bundle is $161.71, the total non-drug component payment for oral drugs is $172.21, the total non-drug component payment for the injectable drugs is $178.65, the total non-drug component payment for the buprenorphine implant insertion is $407.86, the total non-drug component payment for the buprenorphine implant removal is $427.32, and the total non-drug component payment for the buprenorphine implant insertion and removal is $626.97. See Table 18 for a full listing of the final payment rates that we are establishing in this final rule, which reflect the sum of the drug component and non-drug component for each bundled payment. We believe the rates we are finalizing are reflective of an average case, but we recognize that the number of services furnished for patients who have stabilized and are in the maintenance phase of treatment, may be significantly less. However, we note that while the reference codes listed above were considered for the purpose of valuation of the non-drug component of the weekly bundled payments, it is not a requirement for billing these codes (HCPCS codes G2067–G2075) that all of the services described by these reference codes would necessarily be furnished during each week that the bundled payment is billed. Rather, the threshold to bill for the bundled payment is that at least one service in the bundle is furnished during that week, which could be administration of the drug, individual therapy, group therapy, substance use counseling, or toxicology testing.

In response to commenters who stated that the proposed rate for the counseling add-on code was too low, we note that we are finalizing a rate of $30.94, which is based on the CY 2019 PFS non-facility rate for HCPCS code G0396 (*Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes*), when furnished by NPPs, and is higher than the proposed amount for this add-on code. Additionally, we believe that the availability of this add-on code will allow OTPs to receive reimbursement for additional counseling services furnished to patients with more needs, thereby accounting for varying levels of severity of illness. We will be

monitoring the claims data to ensure that use of this add-on code is not being abused.

i. Medication Not Otherwise Specified

In the proposed rule, we stated that we would expect the non-drug component for the medication not otherwise specified bundled payment (HCPCS code G2075) to be consistent with the pricing methodology for the other bundled payments and therefore, to be based on a crosswalk to the TRICARE rate, adjusted for any applicable administration and dispensing fees. For example, for oral medications, we would use the rate for the non-drug services included in the TRICARE methadone bundle, based on an assumption that the drug is also being dispensed daily. For the injectable medications, we similarly stated that we would adjust the TRICARE payment rate for non-drug services using the same methodology we proposed for the bundled payments with injectable medications (to subtract an amount for daily dispensing and add the non-facility Medicare payment rate for administration of the injection). For implantable medications, we stated that we would also use the same methodology we proposed for the bundled payments with implantable medications, with the same crosswalked non-facility Medicare payment rates (for insertion, removal, and insertion and removal). We solicited comments on how the price of the non-drug component of such bundled payments should be determined, in particular the dispensing and/or administration fees, including whether the methodology we proposed for determining the payment rate for the non-drug component of an episode of care that includes a new opioid agonist and antagonist medication (which is based on whether the drug is oral, injectable, or implantable) would be appropriate to use for these new drugs.

We did not receive any comments on our proposal relating to pricing the non-drug component for medication not otherwise specified bundled payments. Consistent with our original proposal, we intend to determine the payment for the non-drug component of the medication not otherwise specified bundle based on whether the drug is oral, injectable, or implantable. However, this payment would be determined using the building block payment methodology that we are adopting in this final rule to determine the non-drug component of the bundled payments for medications that have the same mode of administration.

(c) Partial Episode of Care

For the codes describing partial episodes for methadone and oral buprenorphine, we proposed that the payment rates for the non-drug component would be calculated by taking one half of the payment rate for the non-drug component for the corresponding weekly bundles. We chose one half as the best approximation of the median cost of the services furnished during a partial episode consistent with our proposal to make a partial episode bundled payment when the majority of services described in a beneficiary's treatment plan are not furnished during a specific episode of care. However, we solicited comment on other methods that could be used to calculate these payment rates. We proposed that the payment rates for the drug component of these partial episode bundles would be calculated by taking one half of the payment rate for the drug component of the corresponding weekly bundles.

For the codes describing partial episodes for injectable buprenorphine and naltrexone, we proposed that the payment rates for the drug component would be the same as the payment rate for the drug component of the full weekly bundle so that the OTP would be reimbursed for the cost of the drug that is given at the start of the episode. For the non-drug component, we proposed that the payment rate would be calculated as follows: The TRICARE non-drug component payment rate ($110.96), adjusted to remove the cost of daily administration of an oral drug ($10.50), then divided by two; that amount would be added to the fee that Medicare pays for the administration of an injection (which is currently $16.94 under the CY 2019 non-facility Medicare payment rate for CPT code 96372).

For the codes describing partial episodes for the buprenorphine implant insertion, removal, and insertion and removal, we proposed that the payment rates for the drug component would be the same as the payment rate for the corresponding weekly bundle. For the non-drug component, we proposed that the payment rate would be calculated as follows: The TRICARE non-drug component payment rate ($110.96), adjusted to remove the cost of daily administration of an oral drug ($10.50), then divided by two; that amount would be added to the Medicare non-facility payment rate for the insertion, removal, or insertion and removal of the implants, respectively (based on the non-facility rates for HCPCS codes G0516, G0517, and G0518, which are currently $246.15, $265.61, and $465.26, respectively).

For the code describing a non-drug partial episode of care, we proposed that the payment rate would be calculated by taking one half of the payment rate for the corresponding weekly bundle.

We proposed that the payment rate for the code describing partial episodes for a medication not otherwise specified would be calculated based on whether the medication is oral, injectable or implantable, following the methodology described above for the corresponding type of partial episode. We solicited comments on how partial episodes of care using new drugs with a novel mechanism of action (that is, non-opioid agonist and/or antagonist treatment medications) should be priced. For example, we could use the same approach described previously for pricing new opioid agonist and antagonist medications not otherwise specified, which is to follow the methodology based on whether the drug is oral, injectable or implantable.

We did not receive comments on our proposed methodology for determining payment rates for partial episodes. However, as discussed above, after consideration of the public comments, we are not finalizing our proposal to create partial episodes at this time, and thus will not be finalizing our proposed methodology for pricing partial episodes.

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TABLE 18: OTP Final Code Descriptors and Payment Amounts

HCPCS	Descriptor	Drug Cost*	Non-drug Cost**	Total Cost
G2067	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$35.28	$172.21	$207.49
G2068	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$86.26	$172.21	$258.47
G2069	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$1,578.64	$178.65	$1,757.29
G2070	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$4,918.98	$407.86	$5,326.84
G2071	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$0	$427.32	$427.32
G2072	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$4,918.98	$626.97	$5,545.95
G2073	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$1,164.02	$178.65	$1,342.67
G2074	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$0	$161.71	$161.71
G2075	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	-	-	-
	Intensity Add-on Codes			
G2076	Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a treatment plan that	$0	$179.46	$ 179.46

HCPCS	Descriptor	Drug Cost*	Non-drug Cost**	Total Cost
	includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho- social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.			
G2077	Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$0	$110.28	$ 110.28
G2078	Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$35.28	$0	$35.28
G2079	Take-home supply of buprenorphine (oral); up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$86.26	$0	$86.26
G2080	Each additional 30 minutes of counseling in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$0	$30.94	$30.94

*Methadone drug costs are calculated using ASP data, oral buprenorphine drug costs are calculated using NADAC data, and the other drug costs are calculated using data from the quarterly ASP Drug Pricing Files. The payment amounts in this table are based on data files posted at the time of the drafting of this final rule.

**The non-drug component for the non-drug bundle is based on the sum of the rates under Medicare for the following codes: CPT codes 90832, 90853, 80305, and HCPCS codes G0396 and G0480. For the codes that include oral medications (HCPCS codes G2067 and G2068), we added to that amount the rate for dispensing oral drugs using an approximation of the average dispensing fees under state Medicaid programs, which is $10.50. For the codes that include injectable drugs (HCPCS codes G2069 and G2073), we added to the non-drug bundle amount the fee that Medicare pays for the administration of an injection (which is currently $16.94 under the CY 2019 non-facility Medicare payment rate for CPT code 96372). For the codes that include implantable buprenorphine (HCPCS codes G2070, G2071, and G2072), we added the rates under Medicare for the insertion, removal, and insertion/removal of buprenorphine implants (which is $$246.15, $265.61, and $465.26, respectively, based on the CY 2019 non-facility Medicare payment rates for HCPCS codes G0516, G0517 and G0518). The payment rate for HCPCS code G2076 is based on the CY 2019 non-facility Medicare payment rate for CPT code 99204 plus one presumptive toxicology test (CPT code 80305). The non-drug component for HCPCS code G2077 is based on the CY 2019 non-facility Medicare payment rate for CPT code 99214. The payment rate for HCPCS code G2080 is based on the CY 2019 non-facility Medicare payment rate for HCPCS code G2080 when furnished by an NPP. Additionally, the non-drug component of the bundled payment amounts will be geographically adjusted based on the PFS GAF, this adjustment will also be extended to the non-drug component add-on payments as discussed below.

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(8) Place of Service (POS) Code for Services Furnished at OTPs

In the proposed rule, we explained that we would be creating a new POS code specific to OTPs since there are no existing POS codes that specifically describe OTPs. We indicated that claims for OTP services would include this place of service code. We also noted that POS codes are available for use by all payers. We did not propose to make any differential payment based on the use of this new POS code.

The following is a summary of the comments we received regarding the discussion of creating a new POS and our responses.

Comment: Several commenters supported the plan to create a new POS code that would specifically describe OTPs. A few commenters stated that if non-OTP pharmacies were to dispense MAT drugs covered by an OTP bundle, it is not clear how the OTP POS code will be transmitted to Part D plans or pharmacies so that they will know whether an enrollee is also enrolled in an OTP. Another commenter stated that while POS codes currently distinguish inpatient from outpatient OUD treatment, they do not distinguish between a Medicare-enrolled OTP and a non-Medicare-enrolled OTP and recommended that CMS should consider multiple value sets for POS codes to help retail pharmacies dispense prescriptions and process claims appropriately.

Response: We have created a new place of service code, which will be described as Place of Service code 58 (*Non-residential Opioid Treatment Facility—a location that provides treatment for OUD on an ambulatory basis. Services include methadone and other forms of MAT*). We expect that POS code 58 will be noted on claims

submitted for the HCPCS G codes describing OTP services. Additionally, we note that the G codes describing the OTP bundled payments and add-on codes can only be billed by OTPs and cannot be billed by other providers. We note that POS codes are not specific to Medicare use and may be used by other payers.

In response to the comments about non-OTP pharmacies dispensing MAT drugs included in an OTP bundle, we encourage pharmacies and prescribing OTPs be in close communication in order to ensure proper billing procedures are followed and to prevent duplicative payments. The presence of POS code 58 on retail pharmacy claims will not mean that the pharmacy should process MAT claims any differently than they do now. We appreciate the suggestion to create multiple value sets for POS codes, and will take that under consideration.

c. Duplicative Payments Under Parts B or D

Section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Part B or Part D for items and services furnished by an OTP. In the proposed rule, we noted that many of the individual items or services provided by OTPs that would be included in the bundled payment rates under the proposed policies may also be appropriately available to beneficiaries through other Medicare benefits. Although we recognized the potential for significant program integrity concerns when similar items or services are payable under separate Medicare benefits, we also stated that we believe it is important that any efforts to prevent duplicative payments not inadvertently restrict Medicare beneficiaries' access to other Medicare benefits even for the time period they are being treated by an OTP. For example, a beneficiary receiving counseling or therapy as part of an OTP bundle of services may also be receiving medically reasonable and necessary counseling or therapy as part of a physician's service during the same time period. Similarly, there could be circumstances where Medicare beneficiaries with OUD could receive treatment and/or medication from non-OTP entities that would not result in duplicative payments, presuming that both the OTP and the other entity appropriately furnished separate medically-necessary services or items. Consequently, we explained that we do not believe that provision of the same kinds of services by both an OTP and a separate provider or supplier would itself constitute a duplicative payment.

We explained our belief that duplicative payments would result from the submission of claims to Medicare leading to payment for drugs furnished to a Medicare beneficiary and the associated dispensing fees on a certain date of service to both an OTP and another provider or supplier under a different benefit. In these circumstances, we would consider only one of the claims to be paid for appropriately. Accordingly, for purposes of implementing section 1834(w)(1) of the Act, we proposed to consider payment for medications delivered, administered or dispensed to the beneficiary as part of the OTP bundled payment to be a duplicative payment if delivery, administration or dispensing of the same medications was also separately paid under Medicare Parts B or D. We proposed to codify this policy at § 410.67(d)(4). We acknowledged that some OTPs may negotiate arrangements whereby community pharmacies supply MAT-related medications to OTPs. However, we stated that if the OTP provides medically-necessary MAT-related medications as part of an episode of care, we would expect the OTP to take measures to ensure that there is no claim for payment for these drugs other than as part of the OTP bundled payment. For example, the MAT drugs billed by an OTP as part of a bundled payment should not be reported to or paid under a Part D plan. We stated that we expect that OTPs will take reasonable steps to ensure that the items and services furnished under their care are not reported or billed under a different Medicare benefit. We also noted that CMS intends to monitor for duplicative payments, and would take appropriate action as needed when such duplicative payments are identified. Therefore, we proposed that in cases where a payment for drugs used as part of an OTP's treatment plan is identified as being a duplicative payment because the same costs were paid under a different Medicare benefit, CMS will generally recoup the duplicative payment made to the OTP as the OTP would be in the best position to know whether or not the drug that is included as part of the beneficiary's treatment plan is furnished by the OTP or by another provider or supplier given that the OTP is responsible for managing the beneficiary's overall OUD treatment. We proposed to codify this policy at § 410.67(d)(4). We noted that this general approach would not preclude CMS or other auditors from conducting appropriate oversight of duplicative payments made to the other provider or suppliers, particularly in cases of fraud and/or abuse.

We received a few comments on our proposed policy to address duplicative payments. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal that the OTP should be accountable for ensuring duplicative payments are not made on the basis that OTPs are in the best position to know whether a drug included in the patient's treatment plan is furnished by the OTP.

Response: We thank the commenters for their feedback and support.

Comment: One commenter stated that the new Medicare bundled payments to OTPs should not impact payment for MAT prescriptions rightfully transmitted to a retail pharmacy unless the prescription is from an OTP. The commenter stated that having to determine whether a MAT drug presented to a retail pharmacy should be covered under the new Part B OTP bundle or Part D could introduce a delay in access to treatment. The commenter stated that retail pharmacies should continue to process any MAT prescription under Part D, as they do today. The commenter also stated that prescribers who administer implantable or injectable MAT drugs outside of a SAMHSA-certified OTP would continue to bill these drugs to Part B. Additionally, the commenter questioned if the Medicare bundled payments to OTPs will include MAT drugs that are prescribed within an OTP by a licensed prescriber, but dispensed outside of it.

Response: With regard to the commenter's question concerning MAT drugs prescribed within an OTP but dispensed outside of it, there is no issue of duplicative payment if the OTP has an arrangement with the pharmacy whereby CMS pays the OTP a bundled payment rate and the OTP reimburses the pharmacy through an independent arrangement (in which case the pharmacy would not bill the Part D plan, as it would be reimbursed by the OTP). However, if such an arrangement does not exist, and the pharmacy intends to submit a Part D claim, then the OTP should not bill for an episode of care that includes a drug component but instead should bill for a non-drug episode of care (HCPCS code G2074). Similarly, we note that if the drug administration for a Part B MAT drug occurs outside the OTP and the OTP is not also billing for a weekly bundle that includes that Part B drug, then the administering provider can bill Part B.

Comment: One commenter stated that while they agree with our proposal to recoup duplicative payments from OTPs, CMS should monitor for any unintended impacts to access or other challenges that may result. The commenter stated that CMS must not create a situation in which beneficiaries cannot access needed care because they are receiving OUD treatment through an OTP bundle.

Response: We have explicitly acknowledged that we do not believe a beneficiary receiving the same kinds of services from both an OTP and another provider or supplier would necessarily constitute a duplicative payment. We reiterate, however, that we do have an expectation that OTPs will take reasonable steps to ensure that the items and services furnished under their care are not reported or billed under a different Medicare benefit. For example, OTPs could actively coordinate care and facilitate information exchange between other prescribers, dispensers and plans who prescribe, administer, dispense, or pay for medications for OUD treatment. We also note that OTPs and other health care providers must comply with all applicable laws and regulations, such as the Health Insurance Portability and Accountability Act and the Substance Abuse Confidentiality Regulations (42 CFR part 2). We intend to conduct monitoring to ensure that our policies regarding duplicative payment do not have any such unintended consequences as described by the commenter.

Comment: A few commenters stated that drugs dispensed outside the OTP should not be included in the OTP bundle. One commenter stated that community pharmacies currently face challenges in knowing whether a prescription is from an inpatient OTP or whether the inpatient OTP is prescribing outpatient therapy for a patient who is being discharged. The commenter stated that the best way to avoid duplicate payments from occurring is to limit the OTP bundled payment to drugs dispensed by an OTP facility; similarly the commenter stated that if take-home medications are included in the OTP bundle, they should also be dispensed by the OTP.

Response: We disagree that only medications provided at the OTP should be included in the bundled payment. As indicated above, we are aware that some OTPs have arrangements with pharmacies whereby the OTP reimburses the pharmacy through an independent arrangement. In this case, it is appropriate for the OTP to bill for the weekly bundled payment that corresponds to the medication provided to the beneficiary. We also note that if questions arise regarding the purpose of the prescription, as described by the commenter, the pharmacy should contact the prescribing OTP for any necessary clarifications.

Comment: A few commenters stated that more information is needed to better understand how CMS will monitor and protect against duplicative billing/payment. The commenters recommended that CMS update the guidance in the Medicare Program Integrity Manual to better outline the process through which duplicative payments will be monitored and corrected.

Response: We will consider issuing further guidance either through future rulemaking or subregulatory guidance, as suggested.

Comment: One commenter disagreed that OTPs should be financially accountable for duplicative payments. The commenter stated that OTPs may not have access to prescribing information for every physician or clinician the beneficiary sees outside of the OTP, nor do reporting mechanisms exist for this information in order for OTPs to quickly and efficiently review prior to engaging patients in time-sensitive deployment of OUD treatment.

Response: We reiterate that we have explicitly acknowledged that we do not believe that payments for the same kinds of services from both an OTP and a separate provider or supplier would necessarily result in a duplicative payment. We also emphasize that we have narrowly defined duplicative payment to involve only those circumstances where medications that are delivered, administered or dispensed to a beneficiary are paid as part of the OTP bundled payment, and where the delivery, administration or dispensing of the same medications (that is, same drug, dosage and formulation) is also separately paid under Medicare Part B or Part D for the same beneficiary with the same date of service. As noted earlier, we do not intend to prevent the appropriate billing under Medicare Part B or Part D for individual items or services that could be provided by OTPs as part of an episode of care and included in the bundled payment rate, but that may also be appropriately available to beneficiaries through other Medicare benefits.

Comment: One commenter supported the proposal to hold OTPs accountable for duplicative payments, but stated that CMS should issue a non-enforcement or hold harmless grace period for CY 2020 for audits and other consequences such as Star Ratings related to the new OUD treatment services benefit.

Response: We appreciate the feedback and note that section 1834(w)(1) of the Act expressly requires that we take steps to ensure that no duplicative payments are made. Moreover, as explained above, we have narrowly defined duplicative payment, so we do not believe that a grace period would be necessary for CY 2020.

After consideration of the public comments, we clarifying that our final policy on duplicative payments refers to payment for the same medication for the same beneficiary on the same date of service. Thus we are finalizing our proposal that in cases where a payment for drugs used as part of an OTP's treatment plan is identified as being a duplicative payment because a claim for the same medications for the same beneficiary on the same date of service was paid under a different Medicare benefit, CMS will generally recoup the duplicative payment made to the OTP. We have updated the text at § 410.67(d)(5) to reflect this clarification.

d. Cost Sharing

Section 2005(c) of the SUPPORT Act amended section 1833(a)(1) of the Act, relating to payment of Part B services, by adding a new subparagraph (CC), which specifies with respect to OUD treatment services furnished by an OTP during an episode of care that the amount paid shall be equal to the amount payable under section 1834(w) of the Act less any copayment required as specified by the Secretary. Section 1834(w) of the Act, which was also added by section 2005(c) of the SUPPORT Act, requires that the Secretary pay an amount that is equal to 100 percent of a bundled payment under this part for OUD treatment services. Given these two provisions, we believe that there is flexibility for CMS to set the copayment amount for OTP services either at zero or at an amount above zero. Therefore, we proposed to set the copayment at zero for a time-limited duration (for example, for the duration of the national opioid crisis), as we believe this would minimize barriers to patient access to OUD treatment services. Setting the copayment at zero would also ensure OTP providers receive the full Medicare payment amount for Medicare beneficiaries if secondary payers are not available or do not pay the copayment, especially for those dually eligible for Medicare and Medicaid.[80] We solicited

[80] For those dually eligible individuals in the Qualified Medicare Beneficiary program (7.7

public comment on our proposal to set the copayment at zero for a time-limited duration, such as for the duration of the national opioid crisis, and any other metrics CMS might consider using to determine when to start requiring a copayment. In developing our approach, we also considered other alternatives, such as setting the copayment at a fixed fee calculated based on 20 percent of the payment rate for the bundle, consistent with the standard copayment requirement for other Part B services, or applying a flat dollar copayment amount similar to TRICARE's copayment; however, we recognized that setting the copayment for OUD services at an amount greater than zero could create a barrier to access to treatment for many beneficiaries. We proposed to codify the proposed copayment amount of zero at § 410.67(e). We solicited feedback on our proposal to set the copayment amount for OTP services at zero, and on the alternatives considered, including whether we should consider any of these alternatives for CY 2020 or future years.

Separately, we noted that the Part B deductible would apply for OUD treatment services, as mandated for all Part B services by section 1833(b) of the Act.

We received public comments on the proposals related to cost sharing for the bundled payments for OUD treatment services. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to set the copayment at zero for a time limited duration. A few commenters encouraged CMS to consider setting the copayment at zero permanently, noting that individuals who require the services of an OTP will have difficulty making copayments for a variety of reasons, regardless of whether there is an opioid epidemic across the nation. One commenter noted that if a patient received OUD treatment services outside of an OTP, they would pay 20 percent Part B coinsurance under Medicare at other health care settings or Part D plan cost sharing for any pharmacy-dispensed prescription drugs which may disadvantage other established Medicare provider types. This commenter also noted that OTPs may not be available to patients in all geographic localities, which would seem to be unfair.

Response: We appreciate the support for our proposal. After consideration of the public comments, we are finalizing our proposal to set the copayment at zero for a time limited duration, as we believe this would minimize barriers to patient access to OUD treatment services. Setting the copayment at zero also ensures OTPs receive the full Medicare payment amount for Medicare beneficiaries if secondary payers are not available or do not pay the copayment, especially for those beneficiaries who are dually eligible for Medicare and Medicaid. However, as we explained in the proposed rule, we are interested in setting the copayment at zero for a time limited duration (for example, until such time as the Secretary does not renew the national public health emergency declaration for the continued consequence of the opioid crisis affecting our nation), and intend to address the copayment in future rulemaking at such a time we deem appropriate. Although we appreciate the concern that OUD treatment services furnished in other settings require beneficiary cost sharing, we believe it is important, especially in light of the opioid epidemic, to minimize barriers to patient access to OUD treatment services in such instances that we are able to and note that section 2005 of the SUPPORT Act does not provide authority to waive cost sharing for OUD treatment services furnished in other settings.

Comment: One commenter requested that OTPs be allowed to receive Medicare bad debt payments for any uncollected Part B deductible payments, noting that OTP providers are unlikely to be successful in collecting deductibles for many patients in this population. Another commenter expressed concern that the application of the Part B deductible to OUD treatment services furnished by OTPs might particularly affect dually eligible beneficiaries currently receiving OTP care as they are likely to visit an OTP provider in January, before they hit their annual Part B deductible. This could put them in the position of owing over $100 in January.

Response: We note that bad debts arising from covered services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the Medicare program (42 CFR 413.89(i)). Additionally, we note that the majority of dually eligible individuals are Qualified Medicare Beneficiaries (QMBs), a program in which Medicaid covers the Medicare Part A (if any) and Part B premiums and other Medicare cost-sharing. States may pay for deductibles, coinsurance, and copayments for Medicare services furnished by Medicare providers to QMBs to the extent consistent with the Medicaid State Plan. States have the option to reduce or eliminate the state's Medicare cost sharing payments by adopting policies that limit payment to the lesser of (a) the Medicare cost sharing amount, or (b) the difference between the Medicare payment and the Medicaid rate for the service, consistent with the methodology identified in the state plan. When Medicaid rates are lower this can result in the provider receiving reduced or even no payment for the deductible. Regardless of the amount paid by the state for the deductible, coinsurance, and copayments, sections 1848(g)(3) and 1866(a)(1)(A) of the Act prohibit Medicare providers from billing QMBs for Medicare Parts A and B cost sharing amounts. States may also choose to cover Medicare cost-sharing for certain other full-benefit dually eligible individuals.

As discussed in more detail below, once a provider is enrolled in Medicare, Medicare will crossover the deductible portion of the claim to state Medicaid agencies, and the state will adjudicate the claim. However, as noted above, states often use different HCPCS billing codes for OTP services than Medicare does; in these cases, we note that the state's claims processing system may reject the claim and will notify the provider, who can re-code and resubmit the claim directly to the state.

In summary, we are finalizing our proposal to set the copayment for OUD treatment services furnished by OTPs at zero for a time limited duration, as we believe this would minimize barriers to patient access to OUD treatment services. We are codifying this beneficiary cost-sharing amount at § 410.67(e).

4. Adjustments to Bundled Payment Rates for OUD Treatment Services

The costs of providing OUD treatment services will likely vary over time and depending on the geographic location where the services are furnished. Below we discuss our proposed adjustments to the bundled payment rates to account for these factors.

million of the 12 million dually eligible individuals in 2017), state Medicaid programs cover the Medicare Part A and Part B deductible and coinsurance. However, section 4714 of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides discretion for states to pay Medicare cost-sharing only if the Medicaid payment rate for the service is above the Medicare paid amount for the service. Since most states opt for this discretion, and most Medicaid rates are lower than Medicare's, states often do not pay the provider for the Medicare cost-sharing amount. Providers are further prohibited from collecting the Medicare cost-sharing amount from the beneficiary, effectively having to take a discount compared to the amount received for other Medicare beneficiaries.

a. Locality Adjustment

Section 1834(w)(2) of the Act, as added by section 2005(c) of the SUPPORT Act provides that the Secretary may implement the bundled payment for OUD treatment services furnished by OTPs through one or more bundles based on the type of medications, the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determines appropriate. The cost for the provision of OUD treatment services, like many other healthcare services covered by Medicare, will likely vary across the country based upon the differing cost in a given geographic locality. To account for such geographic cost differences in the provision of services, in a number of payment systems, Medicare routinely applies geographic locality adjustments to the payment rates for particular services. Because we believe OUD treatment services furnished by OTPs will also be subject to varying cost based upon the geographic locality where the services are furnished, in the proposed rule we proposed to apply a geographic locality adjustment to the bundled payment rate for OUD treatment services. We discussed our proposed approach with respect to both the drug component (which reflects payment for the drug) and the non-drug component (which reflects payment for all other services furnished to the beneficiary by the OTP, such as drug administration, counseling, toxicology testing, etc.) of the bundled payment.

(1) Drug Component

Because our proposed approaches for pricing the MAT drugs included in the bundles all reflected national pricing, and because there is no GAF applied to the payment of Part B drugs under the ASP methodology, we did not believe that it would be necessary to adjust the drug component of the bundled payment rates for OTP services based upon geographic locality. Therefore, we proposed not to apply a geographic locality adjustment to the drug component of the bundled payment rate for OTP services. We did not receive any comments on this proposal and are finalizing as proposed not to make any geographic adjustment to the drug component of the bundled payment rates.

(2) Non-Drug Component

Unlike the national pricing of drugs, the costs for the services included in the non-drug component of the OTP bundled payment for OUD treatment services are not constant across all geographic localities. For example, OTPs' costs for rent or employee wages could vary significantly across different localities and could potentially result in disparate costs for the services included in the non-drug component of OUD treatment services. Because the costs of furnishing the services included in the non-drug component of the OTP bundled payment for OUD treatment services will vary based upon the geographic locality in which the services are provided, in the proposed rule we stated that we believed it would be appropriate to apply a geographic locality adjustment to the non-drug component of the bundled payments. We believed that the geographic variation in the cost of the non-drug services provided by OTPs would be similar to the geographic variation in the cost of services furnished in physician offices. Therefore, to account for the differential costs of OUD treatment services across the country, we proposed to adjust the non-drug component of the bundled payment rates for OUD treatment services using an approach similar to the established methodology used to geographically adjust payments under the PFS based upon the location where the service is furnished. The PFS currently provides for an adjustment to the payment for PFS services based upon the fee schedule area in which the service is provided through the use of Geographic Practice Cost Indices (GPCIs), which measure the relative cost differences among localities compared to the national average for each of the three fee schedule components (work, PE, and malpractice).

Although we proposed to adjust the non-drug component of the payments for OUD treatment services using an approach similar to the established methodology used to adjust PFS payment for geographic locality, because GPCIs provide for the application of geographic locality adjustments to the three distinct components of PFS services, and we proposed the OTP bundled payment as a flat rate payment for all OUD treatment services furnished during an episode of care, we explained that a single factor would be required to apply the geographic locality adjustment to the non-drug component of the OTP bundled payment rate. Therefore, to apply a geographic locality adjustment to the non-drug component of the OTP bundled payment for OUD treatment services through a single factor, we proposed to use the Geographic Adjustment Factor (GAF) at § 414.26. Specifically, we proposed to use the GAF to adjust the payment for the non-drug component of the OTP bundled payment to reflect the costs of furnishing the non-drug component of OUD treatment services in each of the PFS fee schedule areas. The GAF is calculated using the GPCIs under the PFS, and is used to account for cost differences in furnishing physicians' services in differing geographic localities. The GAF is calculated for each fee schedule area as the weighted composite of all three GPCIs (work, PE, and malpractice) for that given locality using the national GPCI cost share weights. In developing the proposal, we also considered geographically adjusting the payment for the non-drug component of the OTP bundled payment using only the PE GPCI value for each fee schedule area. However, because the non-drug component of OUD treatment services is comprised of work, PE, and malpractice expenses, we proposed using the GAF as we believe the weighted composite of all three GPCIs reflected in the GAF would be the more appropriate GAF to reflect geographic variations in the cost to OTPs of furnishing OUD treatment services.

The GAF, which is determined under § 414.26, is discussed earlier in section II.D.1. of this final rule and the specific GAF values for each payment locality are posted in Addendum D to this final rule. In developing the proposed geographic locality adjustment for the non-drug component of the OUD treatment services payment rate, we also considered other potential locality adjustments, such as the Inpatient Prospective Payment System (IPPS) hospital wage index. However, we proposed using the GAF as we believed the services provided in an OTP more closely resemble the services provided at a physician office than the services provided in other settings, such as inpatient hospitals. We proposed to codify using the GAF to adjust the non-drug component of the OTP bundled payments to reflect the cost differences in furnishing these services in differing geographic localities at § 410.67(d)(3)(ii). We solicited public comment on the proposal to adjust the non-drug component of the OTP bundled payments for geographic variations in the costs of furnishing OUD treatment services using the GAF. We also solicited comments on any factors, other than the GAF, that could be used to make this payment adjustment.

Additionally, we noted that the majority of OTPs operate in urban localities. In light of this fact, we

explained that we were interested in receiving information on whether rural areas have appropriate access to treatment for OUD. We were particularly interested in any potential limitations on access to care for OUD in rural areas and whether there are additional adjustments to the proposed bundled payments that should be made to account for the costs incurred by OTPs in furnishing OUD treatment services in rural areas. We solicited comment for future consideration on this issue and potential solutions we could consider adopting to address this potential issue through future rulemaking.

We received a few comments on the proposed locality adjustment. The following is a summary of the comments we received and our responses.

Comment: One commenter supported using the GAF to geographically adjust the non-drug component of the bundled payment.

Response: We thank the commenter for their support and feedback.

Comment: One commenter stated that CMS should create a 17 percent rural add-on payment to be applied to the bundled payment rate in low-population density areas where it is difficult to find doctors, nurses, and counselors to treat OUD patients. The commenter noted that Medicare provides a 17 percent rural add-on for inpatient psychiatric facilities which often treat substance abuse cases.

Response: We appreciate the suggestion and may consider whether to propose a rural add-on payment in future rulemaking. In the interim, we note that the current Medicare PFS locality structure contains 34 states with a statewide payment locality, which means that, in these states, the geographic adjustment is the same in all areas, whether urban or rural, thus reducing rural/urban payment differentials within a state. We intend to monitor this issue, and as previously stated, may revisit the issue of a rural add-on payment in the future.

After consideration of the public comments, we are finalizing our proposal to adjust the non-drug component of the OTP bundled payments using the GAF in § 410.67(d)(4)(ii). Additionally, although we did not explicitly address the application of a geographic adjustment in the context of the add-on payment adjustments for non-drug services in the proposed rule, we believe that the same logic regarding the differential costs for those services would apply and should be recognized. As such, we are also finalizing that the add-on payment adjustments for non-drug services will be geographically adjusted as described above.

b. Annual Update

Section 1834(w)(3) of the Act, as added by section 2005(c) of the SUPPORT Act, requires that the Secretary provide an update each year to the OTP bundled payment rates. To fulfill this statutory requirement, we proposed to apply a blended annual update, comprised of distinct updates for the drug and non-drug components of the bundled payment rates, to account for the differing rate of growth in the prices of drugs relative to other services. We proposed that this blended annual update for the OTP bundled payment rates would first apply for determining the CY 2021 OTP bundled payment rates. The specific details of the proposed updates for the drug and non-drug components respectively are discussed in this section.

(1) Drug Component

As stated above, we proposed to establish the pricing of the drug component of the OTP bundled payment rates for OUD treatment services based on CMS pricing mechanisms currently in place. To recognize the potential change in costs of the drugs used in MAT from year to year and to fulfill the requirement to provide an annual update to the OTP bundled payment rates, we proposed to update the payment for the drug component based upon the changes in drug costs reported under the pricing mechanism used to establish the pricing of the drug component of the applicable bundled payment rate, as discussed earlier. For example, if we were to price the drug component of the bundled payment rate for episodes of care using ASP data, the pricing of the drug component for these OTP bundled payments would be updated using the most recently available ASP data at the time of ratesetting for the applicable calendar year. In the proposed rule, we also discussed a number of alternative data sources that could be used to price oral drugs in the drug component of OTP bundled payments in cases when we do not receive manufacturer-submitted ASP pricing data. As an example, if we were to use NADAC data, as discussed as one of the alternatives, to determine the payment for the drug component of the bundled payment for oral drugs in cases when we do not have manufacturer-submitted ASP pricing data, this payment rate would be updated using the most recently available NADAC data at the time of ratesetting for the applicable calendar year.

In developing the proposal to annually update the pricing of the drug component of the OUD treatment services payment rate, we also considered other methodologies, including applying a single uniform update factor to the drug and non-drug components of the proposed payment rates. We ultimately determined not to propose the use of a single uniform update factor, because we believed that it was important to apply an annual update to the payment rates that recognizes the differing rate of growth of drug costs compared to the rate of growth in the cost of the other services. In addition, we also considered annually updating the pricing of the drug component of the OUD treatment services payment rate via an established update factor such as the Producer Price Index (PPI) for chemicals and allied products, analgesics (WPU06380202). The PPI for chemicals and allied products, analgesics is a subset of the PPI produced by the Bureau of Labor Statistics (BLS), which measures the average change over time in the selling prices received by domestic producers for their output. Ultimately we decided against proposing to update the pricing of the drug component of the OUD treatment services payment rate via an established update factor such as the PPI in favor of our proposed approach because we believed the proposed approach would update the pricing of the drug component of the OUD treatment services payment rate in the manner that would be most familiar to stakeholders. We solicited public comment on the proposed approach to updating the drug component of the bundled payment rates. We also solicited comment on possible alternate methodologies for updating the drug component of the payment rate for OUD treatment services, such as use of the PPI for chemicals and allied products, analgesics.

We did not receive any comments on the proposed approach to update the drug component of the bundled payment rates, and are finalizing our proposal to use the most recently available data from the applicable pricing mechanism finalized for drug pricing, as described above, to annually update the drug component of the bundled payment. We are codifying this policy at § 410.67(d)(2)(i), which provides that the payment for the drug component of episodes of care will be determined using the most recent data available at the time of ratesetting for the applicable calendar year.

(2) Non-Drug Component

To account for the potential changing costs of the services included in the non-drug component of the bundled payment rates for OUD treatment services, we proposed to update the non-drug component of the bundled payment for OUD treatment services based upon the Medicare Economic Index (MEI). The MEI is defined in section 1842(i)(3) of the Act and the methodology for computing the MEI is described in § 405.504(d). The MEI is used to update the payment rates for physician services under section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973, may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such a higher level is justified by year-to-year economic changes. The MEI is a fixed-weight input price index that reflects the physicians' own time and the physicians' PEs, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity. The method for calculating the MEI was last revised in the CY 2014 PFS final rule with comment period (78 FR 74264). In developing the proposed update factor for the non-drug component of the OUD treatment services payment rate, we also considered other potential update factors, such as the BLS Consumer Price Index for All Items for Urban Consumers (CPI–U) (Bureau of Labor Statistics #CUUR0000SA0 (*https://www.bls.gov/cpi/data.htm*) and the IPPS hospital market basket reduced by the multifactor productivity adjustment. The CPI–U is a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services. However, we concluded that a healthcare-specific update factor, such as the MEI, would be more appropriate for OTPs than the CPI–U, which measures general inflation, as the MEI would more accurately reflect the change in the prices of goods and services included in the non-drug component of the OTP bundled payments.

Similarly, we believed the MEI would be more appropriate than the IPPS market basket to update the non-drug component of the bundled payment rates as the services provided by an OTP more closely resemble the services provided at a physician office than the services provided by an inpatient hospital. Accordingly, we proposed to update the payment amount for the non-drug component of each of the bundled payment rates for OUD treatment services furnished by OTPs based upon the most recently available historical annual growth in the MEI available at the time of rulemaking. We proposed to codify this proposal at § 410.67(d)(3)(iii).

We received one comment on the annual update for the non-drug component of the bundled payment rate. The following is a summary of the comment we received and our response.

Comment: One commenter disagreed with using the MEI to increase the non-drug component payment and stated that the MEI focuses more narrowly on physician practices. The commenter stated that an OTP's cost structures are more similar to hospital outpatient departments than physician offices. The commenter stated that over time, updating rates by the MEI, which closely mirrors general inflation, will create access to care issues as federal and state mandated OTP costs grow faster than Medicare reimbursements. The commenter also stated that TRICARE utilizes the IPPS annual update factor and if CMS' goal is to align payment with the TRICARE model, it should act consistently and also adopt its annual adjustment policy.

Response: We clarify that CMS' goal is not to align payment with the TRICARE model. As indicated above, section 1834(w)(2) of the Act provides that the Secretary may consider the rates paid to OTPs for comparable services under Medicaid or under TRICARE. As we discussed in the CY 2020 PFS proposed rule, we considered payments for those comparable services in the development of our payment rates. However, we note that we also solicited comment on the scope of private payer OTP coverage and the payment rates private payers have established for OTPs furnishing comparable OUD treatment services for consideration.

We appreciate the commenter's concern about using the MEI to update the non-drug component of the OTP bundled payment rate. Ideally, we would develop a market basket that reflects the detailed cost structures of OTP facilities; however, these data are not currently available. Therefore, we have to use a price index that best approximates the cost of the medical services being provided by the OTP facilities. Although TRICARE uses the IPPS annual update factor, we believe the MEI is a more appropriate index to use to update the non-drug component of the OTP bundled payment rate based on both conceptual and compositional reasons.

From a conceptual standpoint, we believe physicians' services furnished in the office setting more closely align to the OUD treatment services furnished by OTPs as they both encompass minimally invasive medical care such as assessment, counseling, and administering of medications. The MEI measures the market price changes in the inputs used to furnish physicians' services, and represents both the medical and non-medical costs associated with providing this care. In contrast, hospitals engage in complex inpatient and outpatient medical services, such as surgical procedures and emergency room trauma, which are significantly different to the services furnished in OTP facilities. The IPPS market basket reflects these complex services and the non-medical costs associated with managing these large facilities, such as non-medical labor-related services (including but not limited to legal, accounting, financial, and installation and maintenance repair services), which account for almost 25 percent of the IPPS market basket.

From a compositional standpoint, the MEI more closely aligns with the services associated with the OTP payment system. In particular, the MEI does not reflect drug costs (which will be updated separately for OTPs, as discussed previously) as these costs are not reimbursed under the Medicare PFS, for which the MEI was originally developed. The IPPS market basket, however, is an operating market basket that reflects drug costs because these costs are included in the IPPS operating base payment rate. Additionally, the MEI includes PE associated with all operations, including any capital or leasing costs. The IPPS market basket, on the other hand, excludes capital costs because under the IPPS, capital costs are reimbursed separately and the IPPS capital payment rates are updated using the IPPS capital market basket, which reflects the complex capital acquisition and financing methods of IPPS hospitals. Finally, the MEI reflects an adjustment for expected productivity improvements associated with the provision of care (the MEI uses the change in economy-wide private non-farm business multifactor productivity), which, given the similarity in the nature of services furnished in the physician office and OTP settings, OTPs would also be anticipated to be able to achieve. The IPPS market basket does not include a productivity adjustment as that adjustment is applied separately as part of the payment rate update. These compositional differences account for many of the differences between the growth rates of the MEI and the IPPS market basket that the commenter identified as a concern. Because the

differences in growth rates between the IPPS market basket and the MEI are due to these compositional differences, we disagree with the commenter that there is a concern with using the MEI to update the non-drug component of the bundled payment rates. That is, we believe the MEI is an appropriate price index to serve as a proxy for changes in market costs associated with providing OTP services, as it reflects both the medical and non-medical costs of providing noninvasive medical care in a non-inpatient facility.

After consideration of the public comments, we are finalizing the proposal to update the non-drug component of the bundled payment for OUD treatment services based upon the MEI. These policies are codified in § 410.67(d)(4)(iii). Additionally, although we did not explicitly address the application of the annual update to the add-on payment adjustments for non-drug services in the proposed rule, we believe that the same logic regarding the potential changing costs of the services included in the non-drug component of the bundled payment rates is applicable. As such, we are finalizing that the add-on payment adjustments for non-drug services will be subject to the annual update as described above.

In addition to comments on our proposals and the related issues on which we specifically requested public input, we received a number of other public comments related to our implementation of this new Medicare benefit for OUD treatment services furnished in an OTP. Several comments focused on various aspects of how the OTP proposals intersect with Medicaid, those beneficiaries dually eligible for Medicare and Medicaid, Medicare Advantage, and certain requirements related to compliance, quality measurement, and Electronic Health Records. While these issues were not addressed specifically in the proposed rule, we believe it is important to clarify how the OTP policies interface with existing policies under these other programs. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed concerns that in the states that currently cover OTP services under Medicaid, the transition from Medicaid to Medicare as primary payer for those OTP services for dually eligible individuals could result in disruptions to dually eligible individuals' OTP treatment, as well as for OTP providers. Several commenters noted the tight timeframes for OTP providers to enroll in Medicare. For those OTPs currently serving dually eligible individuals under Medicaid, any enrollment backlog may create cash flow problems for these providers, as Medicaid is the payer of last resort, which normally means Medicaid stops paying for a benefit once Medicare starts to cover it. They also noted that the timing of the final regulation would result in less than 60 days to implement needed changes to billing systems. Commenters requested flexibilities during this transition, including a transition period in which OTP providers could still bill Medicaid, with well-publicized transition timelines for a grace period during which improperly submitted claims could be corrected.

Response: We appreciate the concerns expressed by commenters. As discussed in more detail below, Medicaid must pay for OTP services for dually eligible individuals if the service is covered by the Medicaid state plan and the OTP provider is enrolled in Medicaid and not yet enrolled in Medicare.

We will issue guidance to states on strategies to promote continuity of care for dually eligible individuals during this transition period while upholding their responsibilities under Medicaid as the payer of last resort. We will remind states that Medicaid must pay for services delivered to these beneficiaries by OTP providers who are not yet enrolled in Medicare. Recognizing that many OTP providers may not yet be enrolled in Medicare on January 1, 2020, we will recommend that states not impose systems edits to automatically reject claims, (under the assumption that the OTP is Medicare-enrolled and therefore Medicare is the appropriate primary payer for the dually eligible individual) for OTP services furnished to dually eligible individuals at the start of the year. We will encourage states to reach out to their Medicaid-enrolled OTP providers to advise them to enroll as quickly as possible in Medicare. To support continuity of care, we will ask states to offer OTPs options during the interim until Medicare approves the provider enrollment, including billing Medicaid for payment (with the understanding that Medicaid will later recoup the Medicaid payments made, back to the effective date of Medicare provider enrollment, and the provider will bill Medicare instead for those claims), or to hold claims and bill Medicare once the OTP provider is Medicare-enrolled. As requested by the commenters, we will also include in our outreach to OTP providers information about these transition options.

Comment: One commenter who supported a transition period requested that the transition period be extended in cases where OTP providers need to be credentialed and contract with a large number of Medicare Advantage plans, or when Medicaid Managed Care Organizations are involved in covering the Medicare cost-sharing. Commenters noted that unlike Medicare, where there is a single provider enrollment process, it will take significantly longer for OTP providers to become network providers with multiple Medicare Advantage plans, potentially delaying their ability to provide services to dually eligible enrollees of those plans.

Response: We share the concern around ensuring continuity of care for dually eligible individuals who are currently obtaining treatment from an OTP provider through Medicaid and are enrolled in a Medicare Advantage managed care plan. The factors impacting transition are different in Medicare Advantage from those discussed below for Original Medicare. Under section 1852(a) of the Act and 42 CFR 422.100, Medicare Advantage (MA) plans must cover the Medicare OTP benefit because it is a Part B benefit. MA plans may meet this obligation by contracting with OTP providers or making other arrangements with non-contracted OTP providers. Under current MA program requirements, MA plans may furnish OTP access for their enrollees either by establishing direct contracts with OTPs or by arranging access on a non-contract basis. If an MA plan furnishes access to OTPs by contracting with one or more OTPs the MA plan is not necessarily required to contract with all OTP providers in the area, but must ensure that the contracts with OTPs it does have furnish sufficient access and availability to OTP services for its enrollees and are also consistent with the community pattern of care based on the service area where the MA plan is being offered. If an MA plan allows its enrollees to obtain OTP services on a non-contract basis the MA plan must ensure that its enrollees are able to access OTP services that are available within the community pattern of care. (see § 422.112). If a dually eligible individual enrolled in the plan is currently in treatment with an OTP provider with which the plan does not contract, the plan should create a transition process under which the individual can continue to see their current OTP provider while the plan works with the individual to transition to a network provider. Allowing the individual to continue to see their current provider during this transition will ensure continuity of care for this vulnerable population.

Comment: One commenter specifically requested that dually

eligible individuals receiving services from an OTP provider not enrolled in Medicare be able to continue to receive treatment from that provider, and further requested this apply to dually eligible individuals not yet in treatment but who have no Medicare OTP providers in their area.

Response: As noted above, Medicaid must still cover OTP services for dually eligible individuals whose provider is not yet enrolled in Medicare. This flexibility promotes continuity of care for dually eligible individuals already receiving OTP services under Medicaid now, as well as providing beneficiaries access to Medicaid-enrolled OTP providers when there are no Medicare-enrolled OTP providers in their area.

Comment: Some commenters requested clarification on how OTP providers would bill for dually eligible individuals once Medicare starts covering these services on January 1, 2020, including the process for the Part B deductible to be paid by Medicaid.

Response: Once Medicare starts covering OTP services, a Medicare-enrolled OTP provider would bill Medicare for OUD treatment services furnished to dually eligible individuals under Original Medicare. For Original Medicare, if the dually eligible beneficiary has not yet met their annual Medicare Part B deductible, Medicare will automatically ''crossover'' the claim to Medicaid to adjudicate for payment of the deductible. In addition, please see responses to comments below for a discussion of the process when a state is using different billing codes than Medicare, and when an OTP provider is not yet enrolled in Medicare.

For OTP providers serving dually eligible individuals enrolled in Medicare Advantage, there is no automated crossover process. For cost sharing applicable to the OTP benefit under the MA plan, MA plans are required by § 422.504(g)(1) to specify in their contracts with providers that such dually eligible enrollees will not be held liable for Medicare Part A and Part B cost sharing when the State is responsible for paying such amounts, and to inform providers of Medicare and Medicaid benefits, and rules for enrollees eligible for Medicare and Medicaid. We understand most MA plans have not entered into coordination of benefit agreements with state Medicaid agencies. In these instances, the MA plan would not have any means to forward claims for cost sharing directly to state Medicaid programs for payment; and so an OTP provider would need to bill Medicaid directly for the cost sharing that the provider may not collect from the enrollee; this may also mean that the OTP provider has to re-code the claim if the state uses different billing codes than the Medicare Advantage plan uses.

Comment: One commenter specifically requested that the timeframe for state Medicaid agencies to update their respective fee schedules match the Medicare payment methodology to prevent denials when Medicare sends the crossover claim to Medicaid for the deductible.

Response: State Medicaid programs often use different codes and pay differently than Medicare. There is no requirement to match the Medicare payment methodology, but states do need to be able to process claims for the beneficiary's cost-sharing liability for most dually eligible individuals. If the state uses different billing codes, its claims processing system may initially deny the crossover claim, and send a remittance advice to the provider notifying the provider of the denial. The OTP provider should then re-code the claim using the Medicaid billing codes and resubmit to Medicaid for processing.

Comment: A few commenters suggested that CMS offer an expedited process for receiving a Medicare denial, to provide Medicaid with proof that Medicare will not cover the OTP services. A few other commenters also suggested CMS make available an up-to-date-listing of Medicare enrolled OTP providers in each state.

Response: We agree it is important to support OTP providers and states by providing the information needed to facilitate the process for an OTP provider to bill Medicaid for services furnished to a dually eligible individual, when that is permitted. Medicaid will often accept a Medicare claims denial as proof that Medicare will not cover the service, and will process the claim for Medicaid coverage. However, Medicare can only process a claim from a Medicare-enrolled provider, and thus can only issue a claims denial to a Medicare-enrolled provider.

As we note in our response to a prior comment, Medicaid must pay for OUD treatment services furnished by an OTP to a dually eligible individual when the service is covered by the Medicaid state plan and the OTP provider is enrolled in Medicaid, but is not enrolled in Medicare. We agree with the suggestion to make publicly-available and update a list of Medicare-enrolled OTP providers so OTPs and states have evidence that a given provider is not Medicare-enrolled. We anticipate this information will also have value for Medicare beneficiaries seeking OUD treatment services in OTPs. We also note that states already have access to the CMS Provider Enrollment, Chain, and Ownership System (PECOS) provider enrollment system, and can confirm provider enrollment or lack thereof through queries to that system.

Comment: Several commenters expressed concern about the intersection of Medicaid's ''Upper Payment Limit'' (UPL) policy with the proposed Medicare payment rates for OTP services. The commenters noted that most states that cover OTP services have payment rates that are higher than the proposed Medicare payment rates, and expressed a concern that Medicaid's UPL policy requires Medicaid rates to be lower than Medicare's. Commenters noted that unless Medicare significantly increases its proposed rates, state Medicaid agencies would be forced to lower theirs to comply with the UPL. Commenters requested that CMS increase the Medicare rates for services furnished by OTPs to exceed the Medicaid rate in every state, or not apply the UPL requirements to the Medicaid OTP services.

Response: We appreciate the concern expressed by the commenters. However, the UPL requirements do not directly impact payment rates for individual services such as the OUD treatment services furnished by OTPs in the way commenters describe, and states have policy options to address UPL-related concerns. As background, state Medicaid agencies can opt to cover OTP services under the Medicaid clinic benefit or the Medicaid rehabilitation benefit. The Medicaid clinic benefit is subject to a UPL based on estimated Medicare payments, but states demonstrate compliance with this requirement at an aggregate level across the range of services covered under the clinic benefit as a whole for a given year. States are not required to set Medicaid payment lower than Medicare at a service or code-level basis. Within the UPL requirements, states have significant flexibility in how they may pay for individual services or codes or make payments to clinics that specialize in providing certain types of care. As a result, states offering OTP services under the clinic benefit would not be required to reduce their payment rates to be less than Medicare for OTP services. We will issue guidance reminding states that the UPL policy for the clinic benefit applies at the aggregate level, and will work with states to determine how to comply with the UPL if they currently cover OTP under the clinic benefit. For states that offer OTP services under the rehabilitation benefit, we note there is no UPL for that benefit, so the Medicare

payment rate for OTP services does not impact Medicaid payment for those states. As a result, there is no need to adjust the Medicare payment rates for OUD treatment services furnished by OTPs that we are adopting in this final rule to address this concern.

Comment: One commenter suggested CMS provide guidance to states on what the Medicare OTP benefit does and does not cover, to facilitate Medicaid covering specific OTP services for dually eligible individuals that Medicare does not cover.

Response: We acknowledge that states may have a more expansive benefit for services provided by OTPs than Medicare's, and that in those situations, states may continue to cover specific OTP services that Medicare does not. To support a smooth transition, we will provide guidance to states to describe the Medicare OTP benefit and remind them that Medicaid may still cover specific OTP services not covered under the Medicare OTP benefit.

Comment: Several commenters suggested that CMS conduct significant outreach on coordination of benefits; that is, how Medicare will be primary payer and Medicaid will be secondary payer for dually eligible individuals. One commenter further suggested that OTP providers should receive training and technology to facilitate screening patients for Medicare, as well as Medicaid, eligibility and enrollment.

Response: We agree with the need for significant outreach to OTP providers regarding coordination of benefits, and are collaborating with SAMHSA—which certifies OTP providers—to do so. We will explore options around providing technical assistance on connecting eligible clients to Medicare and Medicaid coverage.

Comment: One commenter suggested that as part of supporting the transition from Medicaid to Medicare coverage of OTP services, CMS issue guidance to remind states to continue transportation coverage for full benefit dually eligible individuals receiving services under the Medicare OTP benefit.

Response: As noted elsewhere, Medicare is the primary payer for services that are payable by both Medicare and Medicaid. However, Medicare has a limited non-emergency ambulance transportation benefit. If a full benefit dually eligible individual is obtaining a Medicaid-coverable benefit for which Medicare is the primary payer, the state must assure, in certain circumstances, transportation to the medical service (in the limited instances in which Medicaid does not cover a service Medicare covers, it is optional for states to cover transportation). As a result, when states cover OTP services, and when the applicable criteria are met, Medicaid must assure non-emergency medical transportation for full benefit dually eligible individuals obtaining Medicare-covered OTP services.

Comment: Several commenters supported the proposal to initially set the copayment for OTP services zero, but requested that this policy be made permanent for dually eligible individuals.

Response: We will consider issues on future copayment rates, and on keeping the zero copayment for dually eligible individuals, as part of any future rulemaking on the cost-sharing requirements for the benefit as a whole.

Comment: A commenter raised concerns regarding the January 1, 2020 implementation date for the OTP benefit due to implementation barriers. The commenter stated that MAOs need final payment codes, payment information and clarity regarding any benefit caps or other benefit limits. The commenter further stated that MAOs need additional time to finalize contracting systems and to develop operational details for the benefit.

Response: Although we understand the concern, we do not plan to delay the implementation of this benefit due to the acute need for the OUD treatment services furnished by OTPs. We will work closely with MAOs to ensure timely implementation of this benefit. Plans must provide enrollees with a level of access to Medicare-covered OTP services that is consistent with prevailing community patterns of care in the areas where the network is being offered (§ 422.112(a)(10)). We note that, for CY 2020, Medicare Advantage plans may contract with an OTP provider so long as the requirements for such providers (such as licensure, certification, and other qualifications, etc.) under Titles XVIII and XI of the Act are met. Allowing the individual to continue to see their current provider during this transition will ensure continuity of care for this vulnerable population.

Comment: One commenter recommended that CMS issue a non-enforcement or ''hold harmless'' grace period against plans for Part B vs. Part D determinations for 2020, with respect to audits and other consequences such as Star Ratings related to the new OUD treatment services benefit.

Response: We do not believe it is appropriate for CMS to issue a ''hold harmless'' period regarding the implementation of the new OTP benefit. As we have noted in other responses, we believe there is an urgency in making this benefit available to people struggling with opioid use disorder. CMS will work closely with organizations to ensure a smooth implementation of this benefit. With regard to the Part B versus Part D determination, we remind Medicare Advantage plans that § 422.112(b)(7) requires plans that also cover Part D drugs to coordinate coverage and have a process in place to ensure provision of the covered drug to an enrollee in a timely fashion. CMS clarifies that buprenorphine prescribed by DATA 2000 providers outside of OTPs can continue to be covered under Part D. The DATA 2000 and OTP programs are designed to meet the needs of those needing opioid dependency treatment in different ways. Therefore, because buprenorphine is still covered under Part D when furnished outside an OTP, sponsors should not need to implement new point of service Part B versus Part D pharmacy edits for a buprenorphine claim. In addition, any substantive changes to the Star Ratings measure specifications must be adopted through rulemaking per §§ 422.164 and 423.184.

Comment: A commenter recommended that CMS delay the implementation of the OTP benefit until January 1, 2021, because MA plans did not have an opportunity to account for the new benefit in their 2020 year bids.

Response: In the CY 2020 Call Letter released April 1, 2019 available at the following web link: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf,* CMS issued guidance to MAOs regarding section 2005 of the SUPPORT Act and implementing the OTP benefit. In the Call Letter, CMS reminded plans that opioid use disorder treatment services furnished by OTPs would be covered as a Medicare Part B benefit beginning January 1, 2020. We also stated that MA organizations should prepare their bids using available information and reiterated that MA plans must provide all medically necessary Part A and Part B covered services to enrollees consistent with section 1852 of the Act and the regulations in part 422. As such, MA plans were given the opportunity to account for the new benefit in their 2020 bids and did so when bids were submitted on June 3, 2019.

Comment: A commenter expressed concerns that there may be insufficient number of OTPs available in 2020 who are SAMSHA accredited with a Medicare provider agreement to contract with MA plans.

Response: We note that MA plans will be required to furnish access to OTP

services consistent with what is available to Original Medicare beneficiaries residing in the same geographic area. (see § 422.112) While OTPs will currently not be a specialty included in our evaluation of MA networks, all plan covered services must be furnished consistent with community patterns of care (see § 422.112(a)(10)). This means that a plan's enrollees, who are receiving services from an OTP, cannot be required to travel significantly farther than the distance Original Medicare beneficiaries are required to travel in order to access services from the OTP. MA plans are not required to furnish transportation to the OTP facilities as part of the OTP benefit. However, MA plans can furnish transportation to health care services as a supplemental benefit. In addition, as noted elsewhere, Medicaid must assure, in certain circumstances, non-emergency transportation for a dually eligible individual to obtain a Medicaid-coverable benefit for which Medicare is primary payer.

Comment: A commenter stated that, in order to administer this new benefit, guidance is needed on which services must be covered by an MA plan without cost-sharing and the timelines for coverage without cost-sharing (for example, no more than 12 months of active treatment). The commenter further stated that since OUD treatment is complex and can vary from patient to patient, it is important that plans understand whether there should be no cost-sharing on all components or if there are specific nuances in how to apply the requirement.

Response: MA plans can offer the OTP benefit consistent with the bids which were submitted for CY 2020, including proposed cost-sharing. We note that MA plans must assure that, in instances in which they impose cost-sharing for the OTP benefit, providers do not bill a Qualified Medicare Beneficiary for such cost-sharing. (see § 422.504(g)(1).)

Comment: A commenter requested clarification as to whether OTPs will be billing Medicare Part B—that is, the FFS Medicare program—for services furnished to Medicare Advantage enrollees.

Response: No. OTPs that furnish Medicare covered medically necessary services to MA enrollees will be paid by the enrollees' MA plans. MA plans are required to furnish or cover all benefits that are covered by Medicare Part A and Part B, excluding hospice, for their enrollees. As previously noted, MA plans are required to contract with, or arrange on a non-contract basis for, enrollee access to medically necessary OTP services consistent with the community pattern of care. MA plans may have direct contracts with OTPs in which they negotiate the terms and conditions of payment for the Medicare-covered services furnished by the OTP. An OTP treating an MA enrollee that does not have a contract with the enrollee's MA plan should contact the MA plan to confirm coverage and payment.

Comment: A commenter requested additional information about CMS' expectations of how the OTP benefit will be made available to Medicare Advantage enrollees.

Response: In the CY 2020 Call Letter released on April 1, 2019, CMS issued guidance to MA organizations regarding section 2005 of the SUPPORT Act and implementing the OTP benefit. In the CY 2020 Call Letter, CMS reminded plans that opioid use disorder treatment services furnished by OTPs would be covered as a Medicare Part B benefit by plans beginning January 1, 2020. We also stated that MA organizations should prepare their bids using available information and reiterated that MA plans must provide all medically necessary Part A and Part B covered services to enrollees consistent with section 1852 of the Act and the regulations in part 422.

For dually eligible individuals who may already be receiving OTP services through Medicaid, MA plans should ensure continuity of care for their enrollees any time there is a transition from a non-contracted to a contracted provider. In addition, as noted above, MA plans must assure that in instances in which they impose cost-sharing on the OTP benefit, providers do not bill a Qualified Medicare Beneficiary for such cost-sharing.

Comment: A commenter asks that CMS not allow MA plans to utilize prior authorization (PA) or step therapy for treatment of opioid withdrawal symptoms.

Response: MA plans may use step therapy for Part B drugs when medically appropriate and consistent with the requirements in § 422.136. We also note that when an MA plan processes a coverage request that involves prior authorization or other utilization management requirements, such as step therapy for Part B drugs, the plan's determination on whether to grant approval of a service or a drug for an enrollee constitutes an organization determination under part 422, subpart M, and is subject to appeal. Specifically, as described at § 422.568, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires. CMS is considering strategies we can use to monitor the implementation of the OTP benefit by MA plans and any issues that may impede access to medically necessary treatment of opioid use disorder, including what data might be available to evaluate plan performance.

Comment: A commenter questioned how MA–PD and Prescription Drug Plan sponsors will know what beneficiaries are eligible for this benefit. The commenter proposes that an option would be to provide an indicator in the CMS Medicare Advantage and Prescription Drug data System (MARx), with start and end dates, for beneficiary eligibility for OTP services.

Response: All beneficiaries needing treatment for opioid addiction are eligible for this benefit. We appreciate the data suggestion and will take it into consideration in our on-going implementation of the OTP benefit.

Comment: A commenter questioned how Medicare's managed care plan partners are supposed to reflect the use of this new benefit in their required data submissions.

Response: We will furnish guidance to MA organizations and cost plans on this topic at a later date.

Comment: A commenter requested that since OTPs are currently providing OUD services to Medicare beneficiaries, and that the provider enrollment process would not start until the new Part B benefit is available (January 1, 2020), will CMS allow for payments to OTPs for services delivered in the 30 days prior to their successful enrollment.

Response: As we noted in a previous response, MA plans cannot contract or furnish the Part B OTP services through any OTP that is SAMSHA accredited if that OTP has not yet enrolled in Medicare but the MA plan may cover or furnish services provided by such a provider as a supplemental benefit (§ 422.204(b)(3). Allowing the individual to continue to see their current provider during this transition will ensure continuity of care for this vulnerable population. Furthermore, in some situations, the MA plan may be required by § 422.112(a)(3) to provide out-of-network access for the OTP benefit and we remind MA organizations of their obligations under part 422 regulations to furnish all Part A and Part B benefits, excluding hospice, to their enrollees.

Comment: A commenter noted that the Annual Notice of Change and Evidence of Coverage (ANOC and EOC) documents can play an essential role in updating beneficiaries as to new benefits, but the timing for

implementation of the OTP benefit in 2020 makes this impractical, and instead suggested that CMS undertake a robust public education campaign aimed directly at beneficiaries.

Response: The SUPPORT Act became law in October 2018 and CMS issued guidance to MA organizations in the CY 2020 Draft Call Letter (issued in January 2019) and the CY 2020 Final Call Letter (issued in April 2019) about the requirement to cover the OTP benefit, so MA organizations had sufficient time to plan to include the necessary information in ANOCs and EOCs for 2020. Medicare Advantage plans are required to include the new OTP benefit in their 2020 ANOC/EOC. We are also implementing a comprehensive education campaign regarding the new OTP benefit. Our public education campaign will feature CMS information channels, education resources and outreach leveraging media/stakeholder networks to raise awareness and engage Medicare beneficiaries. Specifically it will include earned media (for example, drop-in article for local/community newspapers), social media (for example, tweets and Facebook posts), beneficiary publications, and outreach to beneficiary partners including State Health Insurance Assistance Programs (SHIPs) across the country, in addition to information available from 1–800–MEDICARE and our consumer website, *http://www.medicare.gov*.

Comment: One commenter requested more information about the compliance criteria, quality metrics, and electronic health record (EHR) requirements that will be used to evaluate OTPs, and whether OTPs will be subject to the requirements of the Quality Payment Program.

Response: We did not propose any compliance criteria, quality metrics, or EHR requirements for OTPs. As OTPs are not one of the eligible clinician types for the Quality Payment Program, they are not able to participate in MIPS or to be a Qualifying APM Participant (QP). However, OTPs may be able to participate in a Center for Medicare and Medicaid Innovation payment model, depending on the eligible participants identified for that specific model, and then would be subject to the requirements of that specific model, which could include quality or EHR-related requirements.

After a thorough review of the above policy considerations reflected in the public comments we received, we are finalizing the proposed provisions to implement the new OTP benefit under section 2005 of the SUPPORT Act, with modifications as described above, at § 410.67, part 489 and part 498.

H. Bundled Payments Under the PFS for Substance Use Disorders

1. Background and Provision

In the CY 2019 PFS proposed rule (83 FR 35730), we solicited comment on creating a bundled episode of care payment for management and counseling treatment for substance use disorders. We received approximately 50 comments on this topic, most of which were supportive of creating a separate bundled payment for these services. Some commenters recommended focusing the bundle on services related to medication assisted treatment (MAT) used in treatment for opioid use disorder (OUD). Several commenters also recommended that we establish higher payment amounts for patients with more complex needs who require more intensive services and management, and also expressed concern that an episode of care that limited the duration of treatment would not be conducive to treating OUD, given the chronic nature of this disorder. Other commenters recommended that we establish separate bundled payments for treatment of substance use disorders that does, and does not, involve MAT.

In response to the public comments, we proposed to establish bundled payments for the overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities. We noted that, if a patient's treatment involves MAT, this bundled payment would not include payment for the medication itself. Billing and payment for medications under Medicare Part B or Part D would remain unchanged. Additionally, payment for medically necessary toxicology testing would not be included in the proposed OUD bundle, and would continue to be billed separately under the Clinical Lab Fee Schedule. We also proposed to implement the new Medicare Part B benefit added by section 2005 of the SUPPORT Act for coverage of certain services furnished by Opioid Treatment Programs (OTPs) beginning in CY 2020. We believe the bundled payment under the PFS for OUD treatment described below will create an avenue for physicians and other health professionals to bill for a bundle of services that is similar to the new bundled OUD treatment services benefit, but not furnished by an OTP. By creating a separate bundled payment for these services under the PFS, we hope to incentivize increased provision of counseling and care coordination for patients with OUD in the office setting, thereby expanding access to OUD care. We note that use of these codes is limited to only beneficiaries diagnosed with OUD; however, we may consider other potential bundles describing services for other substance use disorders in future rulemaking.

To implement this new bundled payment, we proposed to create two HCPCS G-codes to describe monthly bundles of services that include overall management, care coordination, individual and group psychotherapy and counseling for office-based OUD treatment. Although we considered proposing weekly-reported codes to describe a bundle of services that would align with the proposed OTP bundle, we believe that monthly-reported codes will better align with the practice and billing of other types of care management services furnished in office settings and billed under the PFS (for example, behavioral health integration (BHI) services). We believe monthly-reported codes would be less administratively burdensome for practitioners, and more likely to be consistent with care management and prescribing patterns in the office setting (as compared with an OTP) given the increased use of long-acting MAT drugs (such as injectable naltrexone or implanted buprenorphine) in the office setting compared to the OTP setting. We note that these codes should not be billed for beneficiaries who are receiving treatment at an OTP, as we believe that would be duplicative since the bundled payments made to OTPs cover similar services for the treatment of OUD. Based on feedback we received through the comment solicitation, we proposed to create a code to describe the initial month of treatment, which would include intake activities and development of a treatment plan, as well as assessments to aid in development of the treatment plan in addition to care coordination, individual therapy, group therapy, and counseling; a code to describe subsequent months of treatment including care coordination, individual therapy, group therapy, and counseling; and an add-on code that could be billed in circumstances when effective treatment requires additional resources for a particular patient that substantially exceed the resources included in the base codes. In other words, the add-on code would address extraordinary circumstances that are not contemplated by the bundled code. We acknowledge that the course of treatment for OUD is variable, and in some instances, the first several months of treatment may be more resource intensive. We solicited comment on whether we should consider creating a separately billable

code or codes to describe additional resources involved in furnishing OUD treatment-related services after the first month, for example, when substantial revisions to the treatment plan are needed, and what resource inputs we might consider in setting values for such codes.

We believe that, in general, bundled payments create incentives to provide efficient care by mitigating incentives tied to volume of services furnished, and that these incentives can be undermined by creating separate billing mechanisms to account for higher resource costs for particular patients. However, we share some of the concerns raised by commenters that an OUD bundle should not inadvertently limit the appropriate amount of OUD care furnished to patients with varying medical needs. In consideration of this concern, we proposed to create an add-on code to make appropriate payment for additional resource costs in order to mitigate the risks that the bundled OUD payment might limit clinically-indicated patient care for patients that require significantly more care than is in the range of what is typical for the kinds of care described by the base codes. However, we are also interested in comments regarding ways we might better stratify the coding for OUD treatment to reflect the varying needs of patients (based on complexity or frequency of services, for example) while maintaining the full advantage of the bundled payment, including increased efficiency and flexibility in furnishing care.

We anticipate that these services would often be billed by addiction specialty practitioners, but note that these codes are not limited to any particular physician or nonphysician practitioner (NPP) specialty. Additionally, unlike the codes that describe care furnished using the psychiatric collaborative care model (CPT codes 99492, 99493, and 99494), which require consultation with a psychiatric consultant, we did not propose to require consultation with a specialist as a condition of payment for these codes, but we note that consultation with a specialist could be counted toward the minutes required for billing HCPCS codes G2086, G2087, and G2088.

The codes and descriptors for the services are:

- HCPCS code G2086: *Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code G2087: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code G2088: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

For the purposes of valuation for HCPCS codes G2086 and G2087, we are assuming two individual psychotherapy sessions per month and four group psychotherapy sessions per month; however, we understand that the number of therapy and counseling sessions furnished per month will vary among patients and also fluctuate over time based on the individual patient's needs. Consistent with the methodology for pricing other services under the PFS, HCPCS codes G2086, G2087, and G2088 are valued based on what we believe to be a typical case, and we understand that based on variability in patient needs, some patients will require more resources, and some fewer. In order to maintain the advantages inherent in developing a payment bundle, we proposed that the add-on code (HCPCS code G2088) can only be billed when the total time spent by the billing professional and the clinical staff furnishing the OUD treatment services described by the base code exceeds double the minimum amount of service time required to bill the base code for the month. We believe it is appropriate to limit billing of the add-on code to situations where medically necessary OUD treatment services for a particular patient exceed twice the minimum service time for the base code because, as noted above, the add-on code is intended to address extraordinary situations where effective treatment requires additional resources that substantially exceed the resources included in the base codes. For example, the needs of a particular patient in a month may be unusually acute, well beyond the needs of the typical patient; or there may be some months when psychosocial stressors arise that were unforeseen at the time the treatment plan was developed, but warrant additional or more intensive therapy services for the patient. We proposed that when the time requirement is met, HCPCS code G2088 could be billed as an add-on code during the initial month or subsequent months of OUD treatment. Practitioners should document the medical necessity for the use of the add-on code in the patient's medical record. We solicited comment on the proposal.

We proposed to value HCPCS codes G2086, G2087, and G2088 using a building block methodology that sums the work RVUs and direct PE inputs from codes that describe the component services we believe would be typical, consistent with the approach we have previously used in valuing monthly care management services that include face-to-face services within the payment. For HCPCS code G2086, we developed proposed inputs using a crosswalk to CPT code 99492 (*Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.*), which is assigned a work RVU of 1.70, plus CPT code 90832 (*Psychotherapy, 30 minutes with patient*), which is assigned a work RVU of 1.50 (assuming two over the course of the month), and CPT code 90853 (*Group psychotherapy (other than of a multiple-family group)*), which is assigned a work RVU of 0.59 (assuming four over the course of a month), for a work RVU of 7.06. The required minimum number of minutes described in HCPCS code G2086 is also based on a crosswalk to CPT code 99492. Additionally, for HCPCS code G2086, we proposed to use a crosswalk to the direct PE inputs associated with CPT code 99492, CPT code 90832 (times two), and CPT code 90853 (times four). We believe that the work and PE described by these crosswalk codes is analogous to the services described in HCPCS code G2086 because HCPCS code G2086 includes similar care

coordination activities as described in CPT code 99492 and bundles in the psychotherapy services described in CPT codes 90832 and 90853.

We proposed to value HCPCS code G2087 using a crosswalk to CPT code 99493 (*Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies; monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment*), which is assigned a work RVU of 1.53, plus CPT code 90832, which is assigned a work RVU of 1.50 (assuming two over the course of the month), and CPT code 90853, which is assigned a work RVU of 0.59 (assuming four over the course of a month), for a work RVU of 6.89. The required minimum number of minutes described in HCPCS code G2087 is also based on a crosswalk to CPT codes 99493. For HCPCS code G2087, we proposed to use a crosswalk to the direct PE inputs associated with CPT code 99493, CPT code 90832 (times two), and CPT code 90853 (times four). We believe that the work and PE described by these crosswalk codes is analogous to the services described in HCPCS code G2087 because HCPCS code G2087 includes similar care coordination activities as described in CPT code 99493 and bundles in the psychotherapy services described in CPT codes 90832 and 90853.

We proposed to value HCPCS code G2088 using a crosswalk to CPT code 99494 (*Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (List separately in addition to code for primary procedure)*), which is assigned a work RVU of 0.82. The required minimum number of minutes described in HCPCS code G2087 is also based on a crosswalk to CPT codes 99493. For HCPCS code G2088, we proposed to use a crosswalk to the direct PE inputs associated with CPT code 99494. We believe that the work and PE described by this crosswalk code is analogous to the services described in HCPCS code G2088 because HCPCS code G2088 includes similar care coordination activities as described in CPT code 99494.

We understand that many beneficiaries with OUD have comorbidities and may require medically-necessary psychotherapy services for other behavioral health conditions. In order to avoid duplicative billing, we proposed that, when furnished to treat OUD, CPT codes 90832, 90834, 90837, and 90853 may not be reported by the same practitioner for the same beneficiary in the same month as HCPCS codes G2086, G2087, and G2088. We solicited comments on the proposal.

We proposed that practitioners reporting the OUD bundle must furnish a separately reportable initiating visit in association with the onset of OUD treatment, since the bundle requires a level of care coordination that cannot be effective without appropriate evaluation of the patient's needs. This is similar to the requirements for chronic care management (CCM) services (CPT codes 99487, 99489, 99490, and 99491) and BHI services (CPT codes 99484, 99492, 99493, and 99494) finalized in the CY 2017 PFS final rule (81 FR 80239). The initiating visit would establish the beneficiary's relationship with the billing practitioner, ensure the billing practitioner assesses the beneficiary to determine clinical appropriateness of MAT in cases where MAT is being furnished, and provide an opportunity to obtain beneficiary consent to receive care management services (as discussed further below). We proposed that the same services that can serve as the initiating visit for CCM services and BHI services can serve as the initiating visit for the services described by HCPCS codes G2086–G2088. For new patients or patients not seen by the practitioner within a year prior to the commencement of CCM services and BHI services, the billing practitioner must initiate the service during a ''comprehensive'' E/M visit (levels 2 through 5 E/M visits), annual wellness visit (AWV) or initial preventive physical exam (IPPE). The face-to-face visit included in transitional care management (TCM) services (CPT codes 99495 and 99496) also qualifies as a ''comprehensive'' visit for CCM and BHI initiation. We proposed that these visits could similarly serve as the initiating visit for OUD services.

We proposed that the counseling, therapy, and care coordination described in the OUD treatment codes could be provided by professionals who are qualified to provide the services under state law and within their scope of practice ''incident to'' the services of the billing physician or other practitioner. We also proposed that the billing clinician would manage the patient's overall care, as well as supervise any other individuals participating in the treatment, similar to the structure of the BHI codes describing the psychiatric collaborative care model finalized in the CY 2017 PFS final rule (81 FR 80229), in which services are reported by a treating physician or other qualified health care professional and include the services of the treating physician or other qualified health care professional, as well as the services of other professionals who furnish services incident to the services of the treating physician or other qualified health care professional. Additionally, we proposed to add these codes to the list of designated care management services for which we allow general supervision of the non-face-to-face portion of the required services. Consistent with policies for other separately billable care management services under the PFS, because these proposed OUD treatment bundles include non-face-to-face care management components, we proposed that the billing practitioner or clinical staff must document in the beneficiary's medical record that they obtained the beneficiary's consent to receive the services, and that, as part of the consent, they informed the beneficiary that there is cost sharing associated with these services, including potential deductible and coinsurance amounts, for both in-person and non-face-to-face services that are provided.

We proposed to allow any of the individual therapy, group therapy and counseling services included in HCPCS codes G2086, G2087, and G2088 to be furnished via telehealth, as clinically appropriate, in order to increase access to care for beneficiaries. As discussed in section II.F. of this final rule regarding

Telehealth Services, like certain other non-face-to-face PFS services, the components of HCPCS codes G2086 through G2088 describing care coordination are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, these services are not considered telehealth services for purposes of Medicare, and we do not need to consider whether the non-face-to-face aspects of HCPCS codes G2086 through G2088 are similar to other telehealth services. If the non-face-to-face components of HCPCS codes G2086 through G2088 were separately billable, they would not need to be on the Medicare telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology.

Section 2001(a) of the SUPPORT Act amended section 1834(m) of the Act, adding a new paragraph (7) that removes the geographic limitations for telehealth services furnished on or after July 1, 2019, to an individual with a substance use disorder (SUD) diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder. The new paragraph at section 1834(m)(7) of the Act also allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. As discussed in section II.F. of this final rule, Telehealth Services, we proposed to add HCPCS codes G2086, G2087, and G2088 to the list of Medicare Telehealth services. Because certain required services (such as individual psychotherapy or group psychotherapy services) that are included in the proposed OUD bundled payment codes would be furnished to treat a diagnosed SUD, and would ordinarily require a face-to-face encounter, they could be furnished more broadly as telehealth services as permitted under section 1834(m)(7) of the Act.

For these services described above (HCPCS codes G2086, G2087, and G2088), we solicited comment on how these potential codes, descriptors, and payment rates align with state Medicaid coding and payment rates for the purposes of state payment of cost sharing for Medicare-Medicaid dually eligible individuals. Additionally, we understand that treatment for OUD can vary, and that MAT alone has demonstrated efficacy. In cases where a medication such as buprenorphine or naltrexone is used to treat OUD alone, without therapy or counseling, we note that existing applicable codes can be used to furnishing and bill for that care (for example, using E/M visits, in lieu of billing the bundled OUD codes proposed here).

As discussed in section II.G. of this final rule, Medicare Coverage for Certain Services Furnished by Opioid Treatment Programs, we proposed to set the copayment at zero for OUD services furnished by an OTP, given the flexibility in section 1834(w)(1) of the Act for us to set the copayment amount for OTP services either at zero or at an amount above zero. We note that we do not have the statutory authority to eliminate the deductible and coinsurance requirements for the bundled OUD treatment services under the PFS. We acknowledge the potential impact of coinsurance on patient health care decisions and intend to monitor its impact if these proposals were to be finalized.

Finally, we recognize that historically, the CPT Editorial Panel has frequently created CPT codes describing services that we originally established using G-codes and adopted them through the CPT Editorial Panel process. We note that we would consider using any newly available CPT coding to describe services similar to those described here in future rulemaking, as early as CY 2021. We would consider and adopt any such CPT codes through subsequent rulemaking.

Additionally, we understand that in some cases, OUD can first become apparent to practitioners in the emergency department setting. We recognize that there is not specific coding that describes diagnosis of OUD or the initiation of, or referral for, MAT in the emergency department setting. We solicited comment on the use of MAT in the emergency department setting, including initiation of MAT and the potential for either referral or follow-up care, as well as the potential for administration of long-acting MAT agents in this setting, in order to better understand typical practice patterns to help inform whether we should consider making separate payment for such services in future rulemaking. We solicited feedback from stakeholders and the public on other potential bundles describing services for other substance use disorders for our consideration in future rulemaking.

We received public comments on the proposed bundled payments under the PFS for substance use disorders. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for this proposal and a few noted that the PFS bundle would provide an opportunity to increase access to OUD treatment for beneficiaries who live in areas without an OTP, but also encouraged CMS to seek opportunities to more closely align the benefit across OTP and PFS settings before it is introduced and to monitor for any unintended responses to payment incentives, noting differences in the number of psychotherapy sessions included.

Response: We agree with the commenters regarding the importance of alignment in these services when furnished in different settings and note that we are finalizing several changes to the coding and payment for services furnished in an OTP (see section II.G of this final rule), which we believe more closely align the payments made by Medicare for OUD services across settings. For example, we are finalizing using a building block methodology to calculate the payment rate for the OTP bundled payments using Medicare rates, including the rates for CPT codes 90832 and 90853, which were also used to calculate the payment rates HCPCS codes G2086, G2087, and G2088. Additionally, we are finalizing an adjustment to the OTP bundled payments to account for intake activities, similar to activities included in HCPCS code G2086, which describes the initial month of treatment. In response to the comments related to monitoring for unintended responses to payment incentives, we note that we will be monitoring utilization of HCPCS codes G2086, G2087, and G2088 and their interaction with other services, as well as the codes describing bundled payments for services furnished at OTPs.

Comment: A few commenters commended CMS on several aspects of this proposal and urged that the proposed codes and valuations be finalized, and also recommended that CMS consider establishing bundled payment amounts that recognize services for different levels of patient need and different types of practice arrangements, including consultation with specialists.

Response: We thank the commenters for their statements of support. We are finalizing the payment amounts for HCPCS codes G2086, G2087, and G2088 as proposed. We also appreciate the commenters' views on coding for these services, and will consider whether it would be appropriate to create codes describing different levels of patient need and different practice arrangements for possible future rulemaking.

Comment: A few commenters recommended that CMS adjust the payment methodology for these services to account for patient complexity/severity using the American Society of Addiction Medicine (ASAM) Criteria or other equivalent criteria and to account for different types of practice arrangements and emerging technologies. These commenters also recommended that we lower the threshold for billing the add-on code to allow it to be billed when the OUD treatment services described by the base code exceeds 125–150 percent of the minimum time required to bill the base code for the month. Additionally, the commenters recommended that CMS urge health care practitioners to consult with physician addiction specialists, as appropriate, when treating patients with moderate to severe OUD.

Response: After considering public comments, we are finalizing our proposal without modification that HCPCS code G2088 can be billed when the total time spent by the billing professional and the clinical staff furnishing the OUD treatment services described by the base code exceeds double the minimum amount of service time required to bill the base code for the month. We continue to believe it is appropriate to limit billing of the add-on code to situations where medically necessary OUD treatment services for a particular patient exceed twice the minimum service time for the base code because, as noted above, the add-on code is intended to address extraordinary situations where effective treatment requires additional resources that substantially exceed the resources included in the base codes. Additionally, we agree with the commenter's recommendation that practitioners furnishing OUD treatment services should consult with addiction specialists, as clinically appropriate.

Comment: Many commenters requested that CMS allow additional psychotherapy services to be furnished for patients receiving treatment for OUD or another SUD. A few commenters expressed concern that a practitioner would not be able to bill separately for psychotherapy services furnished to beneficiaries with OUD and a co-occurring mental health condition, noting that in rural areas there may not be enough behavioral health providers for a patient to be seen by separate practitioners for SUD and mental health diagnoses.

Response: It is not our intention to limit access to medically necessary services through the creation of bundled payment for OUD treatment services. We clarify that while the psychotherapy services described by CPT codes 90832 (*Psychotherapy, 30 minutes with patient*), 90834 (*Psychotherapy, 45 minutes with patient*), 90837 (*Psychotherapy, 60 minutes with patient*), and 90853 (*Group psychotherapy (other than of a multiple-family group)*) cannot be reported by the same practitioner for the same beneficiary in the same month as the codes describing this bundled episode of care, practitioners can bill for additional psychotherapy furnished for the treatment of OUD using the add-on code (HCPCS code G2088). In cases where psychotherapy services are furnished for co-occurring diagnoses, any of the psychotherapy codes could be billed, as medically reasonable and necessary. We note that practitioners should determine which of the patient's diagnoses they are treating is the primary one being treated during that session in order to decide whether it is appropriate to bill separately for psychotherapy services furnished for co-occurring diagnoses. After reflecting on these and other comments, we also believe it is important to modify our proposal to establish a requirement that at least one psychotherapy service must be furnished in order to bill for HCPCS codes G2086 or G2087. Since the new G codes incorporate the resource costs involved in furnishing psychotherapy services into the payment rate, we believe it is appropriate that a minimum of at least one psychotherapy service be furnished in order to bill for HCPCS codes G2086 or G2087. We note that not all OUD treatment necessarily require provision of regular psychotherapy services for all patients, for example for patients receiving MAT over a long period of time. In these cases, we note that existing coding describing care management services (CPT codes 99484, 99492, 99493, and 99494) and E/M services can be billed for treatment of substance use disorders, including OUD, so we do not believe that this requirement will inhibit access to OUD services.

Comment: A few commenters expressed concern that the proposed G codes will inappropriately limit access to a variety of evidence-based, non-opioid pain management therapies.

Response: We note that the proposed bundled payment codes would not preclude practitioners from furnishing or billing for other non-opioid pain management treatments.

In summary, after consideration of the comments, we are finalizing HCPCS codes G2086, G2087, and G2088 with modifications to establish a requirement that at least one psychotherapy service must be furnished in order to bill for HCPCS codes G2086 or G2087. We are clarifying that practitioners can bill for additional psychotherapy furnished for the treatment of OUD using the add-on code (HCPCS code G2088) and, in cases where psychotherapy services furnished are furnished for co-occurring diagnoses, for any of the psychotherapy codes, as medically reasonable and necessary.

2. Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

In the CY 2018 PFS final rule (82 FR 53169 through 53180), we established payment for General Care Management (CCM) services using HCPCS G0511 which is an RHC and FQHC-specific G code for at least 20 minutes of CCM, complex CCM, or general behavioral health services. Payment for this code is currently set at the average of the non-facility, non-geographically adjusted payment rates for CPT codes 99490, 99487, 99491, and 99484. The types of chronic conditions that are eligible for care management services include mental health or behavioral health conditions, including substance use disorders.

In the CY 2018 PFS final rule with comment period (82 FR 53169 through 53180), we also established payment for psychiatric Collaborative Care Services (CoCM) using HCPCS code G0512, which is an RHC and FQHC specific G-code for at least 70 minutes in the first calendar month, and at least 60 minutes in subsequent calendar months of psychiatric CoCM services. Payment for this code is set at the average of the non-facility, non-geographically adjusted rates for CPT codes 99492 and 99493. The psychiatric CoCM model of care may be used to treat patients with any behavioral health condition that is being treated by the billing practitioner, including substance use disorders.

RHCs and FQHCs can also bill for individual psychotherapy services using CPT codes 90791, 90792, 90832, 90834, 90837, 90839, or 90845, which are billable visits under the RHC all-inclusive rate (AIR) and FQHC Prospective Payment System (PPS) when furnished by an RHC or FQHC practitioner. If a qualified mental health service is furnished on the same day as a qualified primary care service, the RHC or FQHC can bill for 2 visits.

RHCs and FQHCs are engaged primarily in providing services that are furnished typically in a physician's office or an outpatient clinic. As a result of the bundled payment under the PFS for OUD treatment furnished by physicians, we reviewed the applicability of RHCs and FQHCs

furnishing and billing for similar services. Specifically, we considered establishing a new RHC and FQHC specific G code for OUD treatment with the payment rate set at the average of the non-facility, non-geographically adjusted payment rates for G2086 and G2087, beginning on January 1, 2020. The requirements to bill the services would be similar to the requirements under the PFS for G2086 and G2087, including that an initiating visit with a primary care practitioner must occur within one year before OUD services begin, and that consent be obtained before services are furnished.

However, because RHCs and FQHCs that choose to furnish OUD services can continue to report these individual codes when treating OUD, and can also offer their patients comprehensive care coordination services using HCPCS codes G0511 and G0512, we stated that we did not believe that adding a new and separate code to report a bundle of OUD services was necessary. Therefore, we did not propose to add a new G code for a bundle of OUD services.

We received public comments on our decision not to add a new G code for a bundle of OUD services furnished by RHCs and FQHCs. The following is a summary of the comments we received and our responses.

Comment: Commenters requested that we create a new G code for RHCs and FQHCs to bill for a bundle of OUD services. None of these comments were from an RHC or FQHC or a representative of RHCs or FQHCs.

Response: As we have noted, RHCs and FQHCs that provide OUD services to their patients can bill for individual psychotherapy services using a range of CPT codes that are billable visits under the RHC all-inclusive rate (AIR) and FQHC Prospective Payment System (PPS) when furnished by an RHC or FQHC practitioner. These codes can be billed on the same day as a qualified primary care visit, and RHCs and FQHCs can also bill for care management services and receive a payment in addition to their AIR or PPS payment. We did not receive any comments that lead us to conclude that a separate G code for RHCs and FQHCs to bill for OUD services is necessary, or any comments on how such a code would not be duplicative of existing billing mechanisms.

After considering the comments, we are finalizing our proposal not to establish a separate G code for OUD payments to RHCs and FQHCs. If we become aware that a separate code would be beneficial to RHCs and FQHCs that choose to furnish these services, we will again consider this.

I. Physician Supervision for Physician Assistant (PA) Services

1. Background

Section 4072(e) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509, October 21, 1986), added section 1861(s)(2)(K)(i) of the Act to establish a benefit for services furnished by a physician assistant (PA) under the supervision of a physician. We have interpreted this physician supervision requirement in the regulation at § 410.74(a)(2)(iv) to require PA services to be furnished under the general supervision of a physician. This general supervision requirement was based upon another longstanding regulation at § 410.32(b)(3)(i) that defines three levels of supervision for diagnostic tests, which are general, direct and personal supervision. Of these three supervision levels, general supervision is the most lenient. Specifically, the general supervision requirement means that PA services must be furnished under a physician's overall direction and control, but the physician's presence is not required during the performance of PA services.

In the CY 2018 PFS proposed rule (82 FR 34172 through 34173), we published a request for information (RFI) on CMS flexibilities and efficiencies. In response to this RFI, commenters including PA stakeholders informed us about recent changes in the practice of medicine for PAs, particularly regarding physician supervision. These commenters also reached out separately to CMS with their concerns. They stated that PAs are now practicing more autonomously, like nurse practitioners (NPs) and clinical nurse specialists (CNSs), as members of medical teams that often consist of physicians, nonphysician practitioners (NPPs) and other allied health professionals. This changed approach to the delivery of health care services involving PAs has resulted in changes to scope of practice laws in some states for PAs regarding physician supervision. According to these commenters, some states have already updated their requirements for PAs related to physician supervision, some states have made changes and are now silent about their physician supervision requirements, while other states have not yet changed their PA scope of practice in terms of their physician supervision requirements. Overall, these commenters believe that as states continue to make changes to their physician supervision requirements for PAs, the Medicare requirement for general supervision of PA services may become increasingly out of step with current medical practice, imposing a more stringent standard than state laws governing physician supervision of PA services. Furthermore, as currently defined, stakeholders have suggested that the supervision requirement is often misinterpreted or misunderstood in a manner that restricts PAs' ability to practice to the full extent of their education and expertise. The stakeholders have suggested that the current regulatory definition of physician supervision as it applies to PAs could inappropriately restrict the practice of PAs in delivering their professional services to the Medicare population.

We note that we have understood our current policy to require general physician supervision for PA services to fulfill the statutory physician supervision requirement; and we believe that general physician supervision gives PAs flexibility to furnish their professional services without the need for a physician's physical presence or availability. Nonetheless, we appreciate the concerns articulated by stakeholders. To more fully understand the current landscape for medical practice involving PA services and how the current regulatory definition may be problematic, we invited public comments on specific examples of changes in state law and state scope of practice rules that enable PAs to practice more broadly such that those rules are in tension with the Medicare requirement for general physician supervision of PA services that has been in place since the inception of the PA benefit category under Medicare law.

Given the commenters' understanding of ongoing changes underway to the state scope of practice laws regarding physician supervision of PA services, commenters on our CY 2018 RFI have requested that CMS reconsider its interpretation of the statutory requirement that PA services must be furnished under the supervision of a physician to allow PAs to operate similarly to NPs and CNSs, who are required by section 1861(s)(2)(K)(ii) of the Act to furnish their services ''in collaboration'' with a physician. In general, we have interpreted collaboration for this purpose at §§ 410.75(c)(3) and 410.76(c)(3) of our regulations to mean a process in which an NP or CNS (respectively) works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided by state law in which the services are performed. The commenters stated that allowing PA services to be furnished using such a collaborative

process would offer PAs the flexibility necessary to deliver services more effectively under today's health care system in accordance with the scope of practice in the state(s) where they practice, rather than being limited by the system that was in place when PA services were first covered under Medicare Part B over 30 years ago.

2. Summary of Proposal and Final Provisions

After considering the comments we received on the RFI, as well as information we received regarding the scope of practice laws in some states regarding supervision requirements for PAs, we proposed to revise the regulation at § 410.74 that establishes physician supervision requirements for PAs. Specifically, we proposed to revise § 410.74(a)(2) to provide that the statutory physician supervision requirement for PA services at section 1861(s)(2)(K)(i) of the Act would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as required by state law in which the services are performed. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services. Consistent with current rules, such documentation would need to be available to CMS, upon request. This change would substantially align the regulation on physician supervision for PA services at § 410.74(a)(2) with our current regulations on physician collaboration for NP and CNS services at §§ 410.75(c)(3) and 410.76(c)(3). We continue to engage with key stakeholders on this issue and receive information on the expanded role of NPPs as members of the medical team. As we are informed about transitions in state law and scope of practice governing physician supervision, as well as changes in the way that PAs practice, we acknowledge the state's role and autonomy to establish, uphold, and enforce their state laws and PA scope of practice requirements to ensure that an appropriate level of physician oversight occurs when PAs furnish their professional services to Medicare Part B patients. Our policy on this issue largely defers to state law and scope of practice and enables states the flexibility to develop requirements for PA services that are unique and appropriate for their respective state, allowing the states to be accountable for the safety and quality of health care services that PAs furnish.

We received public comments on the proposed physician supervision PA services provisions. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported our proposal overall, to the extent that it considers state law and scope of practice rules for the state in which the services are furnished, to largely conform our interpretation of the statutory physician supervision requirement for PA services as interpreted under regulations at § 410.74(a)(2) with the statutory physician collaboration requirement for NP and CNS services as interpreted under regulations at §§ 410.75(c)(3) and 410.76(c)(3). Commenters indicated that aligning the physician supervision requirement for PA services with the physician collaboration requirement for NPs and CNSs would reduce practical differences in PA and NP/CNS utilization for employers, employees, States and even Medicare patients. They stated that deferring to state law and scope of practice rules for supervision of PA services will enable PAs to practice at the top of their education and expertise, and therefore, assist the State in which they practice with meeting its healthcare workforce needs, particularly in states that include remote rural and underserved areas. These commenters noted that PAs are authorized to provide medical and surgical care in all 50 States and the District of Columbia, and are committed to increasing access to high quality care for all, as well as continuity of care under the changing landscape of healthcare in the U.S. Commenters from 20 States provided evidence of changes in their state laws or scope of practice rules to move away from references to ''physician supervision'' of PAs, and in some cases replacing it with the term, ''physician collaboration'' to describe the PA-physician relationship. Commenters reported such changes in laws and rules for PA supervision in Arizona, California, Colorado, Connecticut, Florida, Idaho, Illinois, Massachusetts, Michigan, Missouri, Montana, Nevada, North Dakota, Oregon, Oklahoma, Rhode Island, South Carolina, Texas, Utah, and Virginia. PA commenters practicing in Kansas, Vermont and Wisconsin indicated that their state laws and scope of practice rules are currently undergoing similar changes that should be effective in 2020 or shortly thereafter. Additionally, these commenters supported CMS' efforts to reduce practice burdens on PAs and to develop regulations for the Medicare program that closely align with the transition in state laws and scope of practice rules for PAs regarding physician supervision. These commenters also noted that the changes being made to state laws and scope of practice rules were recommended by the December 2018 Federal government report on healthcare competition entitled, ''Reforming America's Healthcare System Through Choice and Competition'' available at *https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.* The commenters directed our attention to the specific recommendation in the report that states should consider eliminating requirements for rigid collaborative practice and supervision agreements that are not justified by legitimate health and safety concerns to ensure continuity of care for American healthcare consumers.

Response: We appreciate the commenters' recognition of our efforts to reduce burden on PA practice given the changes in their professional practice since the inception of the Medicare Part B benefit category for PAs under Medicare law. We also appreciate the commenters' support of our proposal to consider state law and scope of practice rules governing PA supervision as an appropriate measure by which to ensure that the physician supervision requirement for PA services under Medicare statute at section 1861(s)(K)(i) of the Act is met. We particularly appreciate the feedback from commenters citing changes that have already been made to state laws and scope of practice rules to address evolution in PA practice. These comments are very helpful to inform our broader understanding of the current healthcare landscape for PAs, and to ensure that the statutory PA physician supervision requirement continues to be met.

Comment: Many commenters who supported our proposal to the extent that it relates to state law and scope of practice rules for physician supervision of PA services disagreed with our proposal to address situations where states are silent about their scope of practice requirements for physician supervision of PA services. Specifically, these commenters urged us to require that, in the absence of state law governing physician supervision of PA services, PAs should be required to document at the practice level, rather than in the medical record, the working relationship that they have with physicians. The commenters expressed

concern that requiring PAs to document their approach in the medical record for every patient that they treat would be a tremendous administrative burden that would have a significantly adverse impact on the PA's ability to deliver care. A few commenters suggested that there should not be a requirement for PAs to document the relationship with any supervising or collaborating physician in every patient chart because such documentation is already provided as part of the practice protocols for PAs that are maintained by the individual State boards of medicine. Furthermore, some commenters recommended that, in the absence of state law addressing physician supervision of PA services, documentation at the practice of the working relationship that PAs have with physicians should be required to address situations where PAs deal with issues outside their scope of practice.

Response: We are clarifying that it is not our intention to create an overly burdensome and unnecessary administrative documentation requirement governing PA physician supervision that results in a hindrance to PA practice. We believe that, in the absence of state law, if there is documentation at the practice which demonstrates the working relationship that PAs have with physicians in furnishing their professional services, then this would be adequate to ensure that the statutory requirement for PA physician supervision is met. However, we believe that in the absence of state law and scope of practice rules governing physician supervision of PAs, the relationship that PAs have with physicians in their practice should be required and documented at the practice for all services that PAs furnish, not solely for services outside their scope of practice.

Comment: One commenter suggested that the PA physician supervision requirement and the NP and CNS physician collaboration requirement should be totally removed so that these health care professionals are not tethered to a physician in any way. This commenter further suggested that the removal of a physician supervision requirement would enable PAs to be able to bill the Medicare program directly for their services like NPs and CNSs, rather than having their services billed by their employer as they currently are.

Response: The Medicare statute sets forth the requirements for physician supervision of PA services and the requirement for physician collaboration for NP and CNS services. As such, we do not have authority to remove those requirements. Additionally, our regulation at § 410.150(b)(15), which is based on the statutory requirements of section 1842(b)(6)(C)(i) of the Act governing payment for PA services requires that a PA's employer or independent contractor must bill the Medicare program for PA services. Accordingly, we are not making changes to requirements for Medicare Part B payment for PA professional services in this final rule.

Comment: Some commenters opposed the proposal overall, and particularly the standard CMS proposed to address the PA physician supervision requirement in the absence of state law and scope of practice rules. These commenters stressed that by just substituting ''physician supervision'' with ''physician collaboration,'' the proposal fails to meet the statutory physician supervision requirement and instead relies on unnecessary variations in standards of care based on differences in state law that are inappropriate for a federal program. These commenters stated that the PA educational curricula are not tailored to developing the responsibilities of PAs to perform all medical services and procedures such as ordering appropriate diagnostic tests and performing highly technical radiology procedures without physician oversight and direction. They believe that physician involvement, either through the physical presence of a physician or availability via telecommunications technology, was necessary to ensure that optimal patient care is not compromised. Additionally, these commenters alluded to high-profile lawsuits against provider organizations in the last year involving PA documentation and billing policy where audits revealed documentation and signature challenges for electronic medical records (EMR) systems in determining whether physician supervision had occurred, and in distinguishing work furnished by a physician, PA or other supplier involved in a patient's care. They suggested that these same obstacles could potentially apply to our proposed medical record documentation standard for PAs to demonstrate, in the absence of state law, the relationship that they have with physicians when furnishing their services. Overall, these commenters stated that the current requirement we established in regulation for a general level of physician supervision to meet the statutory physician supervision requirement for PA services is appropriately consistent with state laws, and enables physicians to maintain the ultimate responsibility for managing patient care without preempting state law and scope of practice rules or inadvertently eliminating any physician oversight of PA services. Accordingly, these commenters urged CMS to maintain the current regulatory standard for general physician supervision of PA services as a clearer standard for physician supervision across-the-board for the Medicare program, and consistent with statutory requirements.

Response: We appreciate the concerns that these commenters raised about our proposal and acknowledge that the statutory requirement for physician supervision of PA services remains in effect. Further, we believe it is appropriate for the Medicare program to recognize and consider the role of states in regulating medical practice and their autonomy to establish, uphold, and enforce their laws and PA scope of practice requirements that are uniquely appropriate for their respective states, just as we ensure that there is appropriate physician supervision of PA services, consistent with the requirement under Medicare law. Additionally, we believe that the commenters' concerns about obstacles for EMR systems to determine whether physician supervision occurred will be mitigated by our decision, as described above, to require in the absence of state law addressing physician supervision of PA services that PAs must document at the practice, rather than in the medical record, their relationship with physicians when furnishing their professional services.

Comment: Some of the commenters who opposed our proposal to require that PAs must document how they handle physician supervision of their services in the absence of state law recommended that we remove the documentation standard as proposed and replace it with a standard that imposes a requirement that PAs work within a health care team led by a physician, given that they believe no state allows PAs to practice independently without any physician supervision or collaboration.

Response: We appreciate this suggestion about how to ensure that physician supervision of PA services occurs in states that are silent about this requirement in their laws or scope of practice requirements for PA professional services. However, we disagree with the commenters' suggestion that, where state law or scope of practice requirements do not address physician supervision of PA services, we should not adopt the proposed requirement that PAs document their approach to working with physicians. We believe it is

important to continue to ensure that the statutory requirement for physician supervision of PA services is met. We also disagree with the commenters' suggestion that we should impose specific requirements that PAs must practice as part of a physician-led health care team. Based on information provided by other commenters, it seems clear that the way PAs practice is evolving, and that state laws and scope of practice rules are being modified to embrace that change. We believe our role and responsibility is to ensure continued compliance with Medicare statutory requirements without placing undue limitations on changes in PA medical practice. As such, we will recognize and consider state law and scope of practice rules principally to ensure that physician supervision occurs without mandating under our regulations that PAs work within a health care team led by a physician.

Comment: Commenters posed various questions about PA services that are outside the scope the proposals we included in the CY 2020 PFS proposed rule. These comments pertained to issues such as PA supervision requirements for both SAMHSA-designated physicians and PAs when furnishing medically-assisted treatment (MAT) services to patients with opioid use disorder; physician supervision requirements for PAs when furnishing services in PA-directed rural health clinics; hospice physician supervision requirements for PAs and the presence of hospice Medical Directors; extending the same considerations for PA physician supervision requirements to pharmacists when furnishing their services incident to the professional services of physicians; and, the Medicare payment implications under this proposal for PA services.

Response: We did not propose changes to the regulations regarding PA services other than the provision that generally addresses the statutory requirement for physician supervision of PA services. Therefore, we are not addressing these other issues in this final rule.

After considering the public comments, we are finalizing our proposal on PA physician supervision, with modifications as described above, to require under § 410.74(a)(2) the following:

- That a PA must furnish their professional services in accordance with state law and state scope of practice rules for PAs in the state in which the PA's professional services are furnished. Any state laws or state scope of practice rules that describe the required practice relationship between physicians and PAs, including explicit supervisory or collaborative practice requirements, describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Act.
- For states with no explicit state law or scope of practice rules regarding physician supervision of PA services, physician supervision is a process in which a PA has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting at the practice level the PA's scope of practice and the working relationships the PA has with the supervising physician/s when furnishing professional services.

J. Review and Verification of Medical Record Documentation

1. Background

In an effort to reduce mandatory and duplicative medical record evaluation and management (E/M) documentation requirements, we finalized an amended regulatory provision at 42 CFR part 415, subpart D, in the CY 2019 PFS final rule (83 FR 59653 through 59654). Specifically, § 415.172(a) requires as a condition of payment under the PFS that the teaching physician (as defined in § 415.152) must be present during certain portions of services that are furnished with the involvement of residents (individuals who are training in a graduate medical education program). Section 415.174(a) provides for an exception to the teaching physician presence requirements in the case of certain E/M services under certain conditions, but requires that the teaching physician must direct and review the care provided by no more than four residents at a time. Sections 415.172(b) and 415.174(a)(6), respectively require that the teaching physician's presence and participation in services involving residents must be documented in the medical record. We amended these regulations to provide that a physician, resident, or nurse may document in the patient's medical record that the teaching physician presence and participation requirements were met. As a result, for E/M visits furnished beginning January 1, 2019, the extent of the teaching physician's participation in services involving residents may be demonstrated by notes in the medical records made by a physician, resident, or nurse.

For the same burden reduction purposes, we issued Change Request (CR) 10412, Transmittal 3971 *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R3971CP.pdf* on February 2, 2018, which revised a paragraph in our manual instructions on ''Teaching Physician Services'' at Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 100.1.1B., to reduce duplicative documentation requirements by allowing a teaching physician to review and verify (sign/date) notes made by a student in a patient's medical record for E/M services, rather than having to re-document the information, largely duplicating the student's notes. We issued corrections to CR 10412 through Transmittal 4068 *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4068CP.pdf* and re-issued the CR on May 31, 2018. Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 100 contains a list of definitions pertinent to teaching physician services.

Following these amendments to our regulations and manual, certain stakeholders raised concerns about the definitions in this section, particularly those for teaching physician, student, and documentation; and when considered in conjunction with the interpretation of the manual provision at Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 100.1.1B., which addresses documentation of E/M services involving students. While there is no regulatory definition of student, the manual instruction defines a student as an individual who participates in an accredited educational program (for example, a medical school) that is not an approved graduate medical education (GME) program. The manual instructions also specify that a student is never considered to be an intern or a resident, and that Medicare does not pay for services furnished by a student (see Section 100.1.1B. for a discussion concerning E/M service documentation performed by students).

As stated in the CY 2020 PFS proposed rule, we are aware that nonphysician practitioners (NPPs) who are authorized under Medicare Part B to furnish and be paid for all levels of E/M services are seeking similar relief from burdensome E/M documentation requirements that would allow them to review and verify medical record notes made by their students, rather than having to re-document the information. These NPPs include nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse-midwives (CNMs), collectively referred to hereafter for purposes of this discussion as advanced practice registered nurses (APRNs), as well as physician assistants (PAs). Subsequent to the publication of the CY

2019 PFS final rule (83 FR 59653 through 59654), through feedback from listening sessions hosted by CMS' Documentation Requirements Simplification workgroup, we began to hear concerns from a variety of stakeholders about the requirements for teaching physician review and verification of documentation added to the medical record by other individuals. Physician and NPP stakeholders expressed concern about the scope of the changes to §§ 415.172(b) and 415.174(a)(6) which authorize only a physician, resident, or nurse to include notes in the medical record to document E/M services furnished by teaching physicians, because they believed that students and other members of the medical team should be similarly permitted to provide E/M medical record documentation. In addition to students, these stakeholders indicated that ''other members of the medical team'' could include individuals who the teaching physician, other physicians, PA and APRN preceptors designate as being appropriate to document services in the medical record, which the billing practitioner would then review and verify, and rely upon for billing purposes.

Subsequent to the publication of the student documentation manual instruction change at section 100.1.1B of the Medicare Claims Processing Manual, representatives of PAs and APRNs requested clarification about whether PA and APRN preceptors and their students were subject to the same E/M documentation requirements as teaching physicians and their medical students. These stakeholders suggested that the reference to ''student'' in the manual instruction on E/M documentation provided by students is ambiguous because it does not specify ''medical student''. These stakeholders also suggested that the definition of ''student'' in section 100 of this manual instruction is ambiguous because PA and APRN preceptors also educate students who are individuals who participate in an accredited educational program that is not an approved GME program. Accordingly, these stakeholders expressed concern that the uncertainty throughout the health care industry, including among our contractors, concerning the student E/M documentation review and verification policy under these manual guidelines results in unequal treatment as compared to teaching physicians. The stakeholders stated that depending on how the manual instruction is interpreted, PA and APRN preceptors may be required to re-document E/M services in full when their students include notes in the medical records, without having the same option that teaching physicians do to simply review and verify medical student documentation.

2. Proposed Provisions and Summaries of and Responses to Public Comments

After considering the concerns expressed by these stakeholders, we noted in the CY 2020 PFS proposed rule that we believe it would be appropriate to provide broad flexibility to the physicians, PAs and APRNs (regardless of whether they are acting in a teaching capacity) who document and who are paid under the PFS for their professional services. Therefore, we proposed to establish a general principle to allow the physician, the PA, or the APRN who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team. We explained that this principle would apply across the spectrum of all Medicare-covered services paid under the PFS. We noted that because the proposal is intended to apply broadly, we proposed to amend regulations for teaching physicians, physicians, PAs, and APRNs to add this new flexibility for medical record documentation requirements for professional services furnished by physicians, PAs and APRNs in all settings.

Specifically, to reflect our simplified and standardized approach to medical record documentation for all professional services furnished by physicians, PAs and APRNs paid under the PFS, we proposed to amend §§ 410.20 (Physicians' services), 410.74 (PA services), 410.75 (NP services), 410.76 (CNS services) and 410.77 (CNM services) to add a new paragraph entitled, ''Medical record documentation.'' We noted that this paragraph would specify that, when furnishing their professional services, the clinician may review and verify (sign/date) notes in a patient's medical record made by other physicians, residents, nurses, students, or other members of the medical team, including notes documenting the practitioner's presence and participation in the services, rather than fully re-documenting the information. We also noted that, while the proposed change addresses who may document services in the medical record, subject to review and verification by the furnishing and billing clinician, it would not modify the scope of, or standards for, the documentation that is needed in the medical record to demonstrate medical necessity of services, or otherwise for purposes of appropriate medical recordkeeping.

We also proposed to make conforming amendments to §§ 415.172(b) and 415.174(a)(6) to also allow physicians, residents, nurses, students, or other members of the medical team to enter information in the medical record that can then be reviewed and verified by a teaching physician without the need for re-documentation.

We received public comments on the proposed Review and Verification of Medical Record Documentation provisions. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the premise for this documentation proposal which they stated almost unanimously would relieve burdensome documentation requirements for PAs, NP, CNSs, and CNMs who are authorized providers under Medicare Part B in that it would minimize ''note bloat'' and clinician burnout, and would allow clinicians to focus their limited time instead on patient care. The commenters stated that enabling physicians other than teaching physicians, PAs and APRNs who furnish and bill for their professional services to review and verify, rather than re-document information included in the medical record by physicians, residents, nurses, students or other members of the medical team is forward-thinking, reflective of the professional healthcare setting and, it eliminates disparities in clinical training opportunities so that a student's experience ranks more than shadowing. The commenters noted that recognizing PA and APRN preceptors in the same manner as teaching physicians regarding student medical record documentation would advance access to quality care for Medicare beneficiaries particularly in rural and underserved areas by granting clinical training opportunities to PA and APRN students. Additionally, these commenters expressed support for this documentation proposal because they believed it would remove the disparity in burden reduction between physicians and clinicians such as PAs and APRNs and, instead would lead to parity for all suppliers of Medicare services paid under the PFS. The commenters also noted that another advantage of these documentation requirements is that they will lead to electronic health records (EHRs) being less cluttered with repetitive notes of little additional clinical use, making more meaningful

information easier for physicians and clinicians to identify while offering greater certainty to medical team members and Medicare Administrative Contractors (MACs) alike.

Response: We appreciate the insight provided by commenters about how the broad flexibility under our proposal would enhance the clinical training opportunities and experience for other physicians, PAs, APRNs and their students while still maintaining the integrity of the information documented in the medical record as it is reviewed and verified by the billing practitioner.

Comment: A commenter supported the merit of the broad flexibility provided under the medical record documentation proposal and suggested that we could improve our proposal by including certified registered nurse anesthetists (CRNAs) and their students under this proposal because CRNAs are also included under the nursing industry's ''APRN'' umbrella. The commenter pointed out that the proposal currently includes NPs, CNSs and CNMs, which are three out of the four categories of APRNs. However, this commenter stated that CRNAs should also be included under this proposal, because not only are CRNAs considered APRNs, they are also authorized by Medicare to furnish and bill for E/M services and all medically necessary services within their state scope of practice. CRNAs regularly complete comprehensive E/M documentation for patients, which is also well within their scope of practice. Accordingly, the commenter believed that since this criterion was a factor in proposing the medical record documentation policy for PAs, NPs, CNSs and CNMs, CRNAs should be included under this policy.

Response: We appreciate the commenter bringing to our attention that CRNAs are another type of clinical nurse that the nursing industry recognizes as an APRN, and that the commenter believed should be included under this medical record documentation proposal. The regulations at § 410.69 interpret the statutory CRNA benefit category at section 1861(bb)(1) of the Act to authorize Medicare Part B payment to CRNAs for anesthesia services and related care that CRNAs are legally authorized to perform by the state in which the services are furnished. We also acknowledge that some states license CRNAs to furnish E/M services as part of the ''related care'' services authorized under their Medicare Part B benefit category. Upon further reflection, we agree that it is appropriate to include CRNAs and their students, as well as other members of their health care team, for purposes of the medical record documentation proposal.

Comment: Several commenters suggested that CMS specifically name the types of students that it intends to include as those who are eligible to make notes in the medical record documentation in order to avoid unnecessary confusion by obscuring the intended scope of students as ''other members of the medical team.'' These commenters stated that explicitly naming the types of clinicians and students for which the documentation they add can be reviewed and verified by the billing professional would eliminate misinterpretation on the part of health systems, care providers, and educators, and would improve both clinical training opportunities and, ultimately, patient care.

Response: We acknowledge that uncertainty in the healthcare industry and for MACs about the specific types of students who were allowed to make notes in the medical record which teaching physicians could review and verify without re-documenting was a factor we considered in proposing to revise the documentation requirements in the CY 2020 PFS proposed rule. We find the comment to be persuasive regarding the need for us to be more explicit regarding the flexibility we intend to establish for other physicians, PAs and APRNs and their students. Given that the initial impetus for our proposal was to address potential confusion about our reference in a manual provision to ''students,'' we would not want to generate any further potential for confusion with this policy. In making our proposal, we referred not only to medical students, but more broadly to students in the disciplines of the clinicians who are authorized to bill the Medicare program for a broad spectrum of health care services, including all level E/M services. We agree with the commenters that it is important to be clear about the scope of this policy and, therefore, we will modify our proposal to explicitly list the types of students for which the medical records documentation policy applies rather than using a generic reference to ''students.'' Therefore, at §§ 410.20, 410.69, 410.74, 410.75, 410.76 and 410.77, we will modify our proposed amendments to the regulation to specify the types of students who may make notes in the medical record that may then be reviewed and verified, rather than re-documented, by the billing clinician.

Comment: Several commenters suggested that CMS specify that physicians, PAs, and APRNs may sign off on only those notes in the medical record made by someone of their same provider type or discipline. For example, a PA may only review and verify information included in a patient's chart by another PA or PA student. One of these commenters stated that CMS should withhold any documentation requirement changes until the agency establishes guidelines in future rulemaking that clarify the circumstances under which a clinician would be permitted to review and verify medical record documentation. Conversely, a few of these same commenters questioned the proposal and stated that it is unclear whether a PA or APRN can sign off on any resident or student documentation regardless of their credential level. For example, a PA would be able to attest and bill for work that was performed by a senior resident who is training to become a medical doctor. A few of these commenters warned that scope of practice laws may impose documentation requirements that lead to physicians and clinicians only reviewing documentation of their own student types and not that of other disciplines. Furthermore, the commenters stated that the teaching physician services requirements do not permit PAs and APRNs to formally act as teaching physicians.

Response: We did not propose any limitations that would restrict a billing professional to only reviewing and verifying documentation in the medical record entered by health care team members practicing or training within their same specialty or discipline. We believe that this type of limitation on our proposal would defeat our intended purpose to provide broad flexibility, establishing a generalized principle for medical record documentation for all professional services paid under the Medicare PFS in all settings. Therefore, we disagree with the commenters' recommendation, and are not finalizing restrictions on the scope of medical record documentation entered by members of the medical team that can be reviewed and verified by the billing professional. Additionally, our documentation proposal does not address any applicable billing or payment requirements for the work or services that others furnish in connection with the professional services that are billed by teaching physicians, other physicians, PAs or APRNs. Rather, our proposal is limited to addressing who is authorized, for purposes of the Medicare program, to review and verify documentation in the medical record entered by certain individuals, without having to re-document the information.

Comment: Similarly, several commenters representing physicians supported making the proposed changes to medical record documentation requirements for physicians only, and not for PAs and APRNs. They stated that only physicians submitting a claim for services are responsible and appropriately trained to review and verify documentation in the medical record provided by physicians, residents, nurses, students, or other members of the medical team across the spectrum of all Medicare-covered services paid under the PFS. They maintained that safeguards must be in place to ensure the medical record includes accurate documentation of clinical findings, treatments, and ongoing care plans by all members of the medical team.

Response: We note that the billing professional, in submitting a claim to Medicare for services paid under the PFS, is responsible for the accuracy of the information included on that claim. While we appreciate the perspective of these commenters, stakeholders and other commenters have made it clear to us that the role of PAs and APRNs has changed to the point that our current regulations present an unintended burden for billing practitioners, unnecessarily requiring them to re-document information entered into the medical record by physicians, residents, nurses, students, and other members of the medical team when it would be sufficient for them to simply review and verify it. Therefore, we are not establishing a requirement in this final rule that only a billing physician may review and verify documentation in the medical record added by physicians, residents, nurses, students, and other members of the medical team.

Comment: Commenters requested clarification about whether multiple students and residents can enter documentation into the medical record on the same day and during the same office visit. One commenter stated that, currently, MACs or auditing agencies will deny PA or APRN services when furnished on the same day as a service billed by a physician regardless of the physician's specialty.

Response: We appreciate the information and suggestion provided by these commenters. We did not propose a limitation on how many members of the medical team can enter information in the medical record for a given date of service or patient encounter, and do not believe such a limitation is warranted. We did not address the scope of services that can be billed for a patient on the same date of service. Therefore, this aspect of the comment is outside the scope of the proposed rule and we will not address it in this final rule.

Comment: Several commenters encouraged CMS to re-examine the current requirements regarding documentation of the billing practitioner's physical presence and participation in certain E/M services and procedures. The commenters stated that this physical presence and participation requirement results in significant burden for teaching physicians and PA and APRN preceptors when their students are participating in patient care. These commenters stated that while physical presence and participation of physicians and practitioners in the clinic is critical for safe patient care, presence in the examination room during documentation is onerous and unnecessary. The commenters also noted that this requirement greatly diminishes the learning experience for students, as they do not develop the ability to think or operate independently, formulate diagnoses, and generate treatment plans, producing less experienced graduate clinicians who are not as prepared as they could be to provide care on their own.

Response: We did not propose any changes to requirements pertaining to the documentation of physical presence and participation for certain E/M services and procedures at §§ 415.172 and 415.174, and we are not addressing these requirements in this final rule.

Comment: A commenter questioned whether this proposal recognizes ''scribes'' other than a medical assistant or a registered nurse for purposes of entering notes in a patient's medical record. The commenter defined a scribe as an independent individual assisting a single care provider, and expressed concern that utilizing clinical support staff as a scribe to document services will lead to dissatisfaction of employees and loss of clinical support staff, which would adversely affect the shortage in clinical support staff that already exists. Likewise, a commenter suggested that CMS should explicitly include dieticians and nutritionists among the other members of the medical team who are eligible to enter notes in the medical record.

Response: We proposed broad flexibility for teaching physicians, other physicians, PAs and APRNs to use their discretion in identifying, for each particular case, the individuals who are serving as members of the medical team, potentially including scribes, dieticians, nutritionists, or other members of their medical team. Although we are modifying our proposal to clarify the scope of students that may be considered members of the medical team for purposes of this documentation policy as explained above, we intentionally did not propose to specify who can be included as a member of the medical team.

Comment: One commenter questioned whether their assumption is correct that this proposal applies to all types of services (that is, procedures, E/M services, and diagnostic services).

Response: The commenter's assumption is accurate; our proposed medical record documentation policy would apply broadly to all services of physicians, PAs and APRNs, regardless of the type of service (E/M, procedure, diagnostic test) or the setting in which the service is furnished.

Comment: We received a number of comments that were outside the scope of the CY 2020 PFS proposed rule.

Response: We appreciate and will consider these comments for other purposes including possible future rulemaking.

After considering the comments, we are finalizing our proposal with a couple of modifications. We are explicitly naming PA and NP, CNS, CNM and CRNA students as APRN students, along with medical students, as the types of students who may document notes in a patient's medical record that may be reviewed and verified rather than re-documented by the billing professional; and revising §§ 410.20, 410.69, 410.74, 410.75, 410.76, 410.77, 415.172 and 415.174 to reflect this change. Additionally, similar to the revisions we are making to the regulations at §§ 410.20, 410.69, 410.74, 410.75, 410.76, 410.77, 415.172 and 415.174, we are amending our regulation at § 410.69 to add a new paragraph (5) under the definition of CRNA to include CRNAs as a category of APRNs for purposes of this policy, and to include CRNA students under the reference to APRN students.

K. Care Management Services

1. Background

In recent years, we have updated PFS payment policies to improve payment for care management and care coordination. Working with the CPT Editorial Panel and other clinicians, we have expanded the suite of codes describing these services. New CPT codes were created that distinguish between services that are face-to-face; represent a single encounter, monthly service or both; are timed services; represent primary care versus specialty care; address specific conditions; and represent the work of the billing

practitioner, their clinical staff, or both (*see* Table 19). Additional information regarding recent new codes and associated PFS payment rules is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html.*

TABLE 19: Summary of Special Care Management Codes

Service	Summary
Care Plan Oversight (CPO) (also referred to as Home Health Supervision, Hospice Supervision) (HCPCS Codes G0181, G0182)	Supervision of home health, hospice, per month
ESRD Monthly Services (CPT Codes 90951-70)	ESRD management, with and without face-to-face visits, by age, per month
Transitional Care Management (TCM) (adopted in 2013) (CPT Codes 99495, 99496)	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit, once per patient within 30 days post-discharge
Chronic Care Management (CCM) (adopted in 2015, 2017, 2019) (CPT Codes 99487, 99489, 99490, 99491)	Management of all care for patients with two or more serious chronic conditions, timed, per month
Advance Care Planning (ACP) (adopted in 2016) (CPT Codes 99497, 99498)	Counseling/discussing advance directives, face-to-face, timed
Behavioral Health Integration (BHI) (adopted in 2017) (CPT Codes 99484, 99492, 99493, 99494)	Management of behavioral health conditions(s), timed, per month
Assessment/Care Planning for Cognitive Impairment (adopted in 2017) (CPT Code 99483)	Assessment and care planning of cognitive impairment, face-to-face visit
Prolonged Evaluation & Management (E/M) Without Direct Patient Contact (adopted in 2017) (CPT Codes 99358, 99359)	Non-face-to-face E/M work related to a face-to-face visit, timed
Remote Physiologic Monitoring (adopted beginning 2018 with CPT Code 99091; in 2019, added CPT codes 99453, 99454, 99457; for CY 2020, will add CPT code 99458)	Analysis of patient data used to develop and manage a treatment plan
Interprofessional Consultation (adopted in 2019) (CPT Codes 99446, 99447, 99448, 99449, 99451, 99452)	Inter-practitioner consultation

Based on our review of the Medicare claims data we estimate that approximately 3 million unique beneficiaries (9 percent of the Medicare fee-for-service (FFS) population) receive these services annually, with higher use of chronic care management (CCM), transitional care management (TCM), and advance care planning (ACP) services. We believe gaps remain in coding and payment, such as for care management of patients having a single, serious, or complex chronic condition. In this final rule, we continue our ongoing work in this area through code set refinement related to TCM services and CCM services, in addition to new coding for principal care management (PCM) services, and addressing chronic care remote physiologic monitoring (RPM) services.

2. Transitional Care Management (TCM) Services

Utilization of TCM services has increased each year since CMS established coding and began paying separately for TCM services. There were almost 300,000 TCM professional claims during 2013, the first year of TCM services, and almost 1.3 million professional claims during 2018, the most recent year of complete claims data. However, a recent analysis of TCM claims data by Bindman and Cox [81] found that use of TCM services is low when compared to the number of Medicare beneficiaries with eligible discharges. Bindman and Cox noted that the beneficiaries who received TCM services demonstrated reduced readmission rates, lower mortality, and decreased health care costs. Based upon these findings, we believe that increasing utilization of medically necessary TCM services could positively affect patient outcomes.

In developing the proposal designed to increase utilization of TCM services, we considered factors that could contribute to low utilization. Bindman and Cox identified two likely contributing factors: The administrative burdens associated with billing TCM services and the payment amount to physicians for furnishing these services.

We focused initially on the requirements for billing TCM services. In reviewing TCM billing requirements, we noted that we had established in the CY 2013 PFS final rule with comment period a list of 57 HCPCS codes that could not be billed during the 30-day period covered by TCM services by the same practitioner reporting TCM (77 FR 68990). This list mirrored reporting restrictions put in place by the CPT Editorial Panel for the TCM codes. At the time we established separate payment for the TCM CPT codes, we agreed with the CPT Editorial Panel that the services described by the 57 codes could be overlapping and duplicative with TCM in their definition and scope. Additionally, many of the codes were not separately payable or covered under the PFS so even if they had been reported for PFS payment, they would not have been paid separately (*see,* for example, 77 FR 68985).

[81] Bindman, AB, Cox DF. Changes in health care costs and mortality associated with transitional care management services after a discharge among Medicare beneficiaries [published online July 30, 2018]. *JAMA Intern Med,* doi:10.1001/jamainternmed.2018.2572.

In response to those initial concerns, we adopted billing restrictions to avoid duplicative billing and payment for covered services. In our recent analysis of the services associated with the 57 codes, we found that the majority of codes on the list are either bundled, noncovered by Medicare, or invalid for Medicare payment purposes. Table 20 provides detailed information regarding the subset of these codes that would be separately payable under the PFS (Status Indicator ''A'') and, as such, are the focus of CY 2020 policy for TCM. Fourteen (14) codes on the list represent active codes that are paid separately under the PFS and that upon reconsideration, we believe do not substantially overlap with TCM services and should be separately payable alongside medically necessary TCM. For example, CPT code 99358 (*Prolonged E/M service before and/or after direct patient care; first hour; non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service*) would allow the physician or other qualified healthcare professional extra time to review records and manage patient support services after the face-to-face visit required as part of TCM services.

After review of the services described by the 14 HCPCS codes, we determined that the 14 codes, when medically necessary, may complement TCM services rather than substantially overlap or duplicate services. We also believed removing the billing restrictions associated with the 14 codes might increase use of TCM services.

TABLE 20: 14 HCPCS Codes that Currently Cannot be Billed Concurrently with TCM by the Same Practitioner and are Active Codes Payable by Medicare PFS

Code Family	HCPCS Code	Descriptor
Prolonged Services without Direct Patient Contact	99358	Prolonged E/M service before and/or after direct patient care; first hour; non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service
	99359	Prolonged E/M service before and/or after direct patient care; each additional 30 minutes beyond the first hour of prolonged services
Home and Outpatient International Normalized Ratio (INR) Monitoring Services	93792	Patient/caregiver training for initiation of home INR monitoring
	93793	Anticoagulant management for a patient taking warfarin; includes review and interpretation of a new home, office, or lab INR test result, patient instructions, dosage adjustment and scheduling of additional test(s)
End Stage Renal Disease Services (patients who are 20+ years)	90960	ESRD related services monthly with 4 or more face-to-face visits per month; for patients 20 years and older
	90961	ESRD related services monthly with 2-3 face-to-face visits per month; for patients 20 years and older
	90962	ESRD related services with 1 face-to-face visit per month; for patients 20 years and older
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older
	90970	ESRD related services for dialysis less than a full month of service; per day; for patient 20 years and older
*Analysis of Data	99091	Collection and interpretation of physiologic data
Complex Chronic Care Management Services	99487	Complex Chronic Care with 60 minutes of clinical staff time per calendar month
	99489	Complex Chronic Care; additional 30 minutes of clinical staff time per month
Care Plan Oversight Services	G0181	Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities within a calendar month; 30+ minutes
	G0182	Physician supervision of a patient receiving Medicare-covered hospice services (Pt not present) requiring complex and multidisciplinary care modalities; within a calendar month; 30+ minutes

* In CY 2018, this code was unbundled and added as an active code to the PFS. The 2019 CPT Manual (p. 42) indicates the code cannot be billed concurrently with either TCM code.

Thus, with the goal of increasing medically appropriate use of TCM services, we proposed to revise our billing requirements for TCM by allowing TCM codes to be billed concurrently with any of these 14 codes. In the proposed rule, we solicited comment on four questions related to current billing policies. They included:

- Does overlap of services exist, and if so, which services should be

restricted from being billed concurrently with TCM?

- Does overlap depend upon whether the same or a different practitioner reports the services; we note that CPT reporting rules generally apply at the practitioner level?
- Should our policy differ based upon whether the same or different practitioner reports the services?
- Does the newest CPT code in the chronic care management services family (CPT code 99491 for CCM by a physician or other qualified health professional, established in 2019) overlap with TCM or should it be reportable and separately payable in the same service period?

The second part of our analysis examined how current payment rates for TCM might negatively affect the appropriate utilization of TCM services, an idea proposed by Bindman and Cox. Although we sought comment previously about factors affecting utilization of CCM and TCM services, we received too few comments related specifically to TCM to know if payment affected use of the service.

As part of a regular RUC review of new technologies or services during 2018, CPT code 99495 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*) and CPT code 99496 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within 7 calendar days of discharge*) were resurveyed. For this RUC resurvey, several years of claims data were available and clinicians had more experience to inform their views about the work required to furnish TCM services. Based upon the results of the 2018 RUC survey of the TCM codes, the RUC recommended a slight increase in work RVUs for both codes. We believe the results from the new survey better reflect the work involved in furnishing TCM services as care management services. Thus, also for CY 2020, we proposed the RUC-recommended work RVU of 2.36 for CPT code 99495 and the RUC-recommended work RVU of 3.10 for CPT code 99496. We did not propose any PE refinements to the TCM codes.

We received public comments to our proposed policies and questions. The following is a summary of the comments we received.

Comment: With regard to the questions about billing requirements, most commenters wrote in support of our proposal to remove billing restrictions associated with the 14 codes that, at present, cannot be billed concurrently with TCM. A few commenters indicated that overlap, if it does exist, is minimal. Some commenters cautioned that our suggested change to billing might cause increased confusion for payers other than Medicare and suggested that CMS instead work with the CPT Editorial Panel to review and possibly revise the restrictions. In response to our questions about overlap in services, commenters reported that overlap is not dependent upon whether the same or a different practitioner reports the services. Commenters added that policy should not be based upon what practitioner reports the services. Finally, commenters expressed support for allowing CPT code 99491 *(Chronic care management services, provided personally by a physician or other qualified healthcare professional, at least 30 minutes of professional time per calendar month)* to be reportable and separately payable in the same service period as TCM.

Response: We thank the many commenters for their comments regarding ways to increase utilization of TCM services. Our goal in proposing to remove the current billing restrictions was to increase appropriate utilization of TCM services, particularly in light of the potential benefits noted by Bindman and Cox. Since publication of the CY 2020 PFS proposed rule, we have identified two chronic care management codes, CPT codes 99490 and 99491 that are not listed in the TCM section of the CPT manual as being restricted from concurrent billing. However, in the care management section of the 2019 CPT Manual, prefatory language indicates that neither CPT code 99495 nor 99496 (*see,* page 50) can be billed during the same month as CPT code 99490. Given our proposal to remove current billing restrictions, we believe that both CPT codes 99490 and the new 99491 should be added to the list of care management codes that can be billed concurrently with TCM when relevant and medically necessary.

We continue to believe that revising the billing requirements and allowing TCM codes to be billed concurrently with codes currently restricted will help to achieve our goal and may result in other payers implementing similar changes. Additionally, this change may lead the CPT Editorial Panel to consider revising the current prohibitions on billing TCM with certain codes.

Comment: Commenters uniformly recommended that CMS finalize the increased valuations for the two TCM codes. Commenters expressed support for the agency's goal of increasing utilization of medically necessary TCM services given the potential benefits the services provide to patients as noted by Bindman and Cox.

Response: We believe that adopting the RUC-recommended increase in valuation of the work RVUs will support our goal of increasing medically necessary TCM services.

After considering public comments on our questions and proposals, and in light of our goal of increasing utilization of TCM services, we are finalizing our proposal to allow concurrent billing of the care management codes currently restricted from being billed with TCM. This includes allowing concurrent billing of TCM with the 14 codes specified in Table 20, as well as CPT codes 99490 and 99491, which we have identified as codes that also fit this policy. We are finalizing for both TCM codes the proposed increases in work RVUs and the RUC-recommended direct PE inputs. We look forward to working with the public and other stakeholders to potentially further refine our billing policies through future notice and comment rulemaking.

3. Chronic Care Management (CCM) Services

CCM services are comprehensive care coordination services per calendar month, furnished by a physician or nonphysician practitioner (NPP) managing overall care and their clinical staff, for patients with two or more serious chronic conditions. There are currently two general subsets of codes: One for non-complex chronic care management (starting in 2015, with a new code for 2019) and a set of codes for complex chronic care management (starting in 2017). Tables 21 and 22 list the applicable current codes (abbreviated) and provide a high-level summary of the CCM service elements. We refer readers to the following website for more comprehensive information regarding the CCM codes and the existing requirements for billing them to the PFS, available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html.*

TABLE 21: Chronic Care Management Codes (CY 2019)

CPT Code	Summary
99490 ("Non-Complex CCM")	Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional (QHP), per calendar month
99491 ("Non-Complex CCM")	Chronic care management services, provided personally by a physician or other QHP, at least 30 minutes of physician or other QHP time, per calendar month
99487 ("Complex CCM")	Complex chronic care management services, first 60 minutes of clinical staff time with moderate or high complexity medical decision making by the reporting practitioner
99489 ("Complex CCM")	Complex chronic care management services, each additional 30 minutes of clinical staff time with moderate or high complexity medical decision making by the reporting practitioner

TABLE 22: Chronic Care Management Services Summary

CCM Service Summary*
Verbal Consent • Inform regarding availability of the service; that only one practitioner can bill per month; the right to stop services effective at the end of any service period; and that cost sharing applies (if no supplemental insurance). • Document that consent was obtained.
Initiating Visit for New Patients (separately paid)
Certified Electronic Health Record (EHR) Use • Structured Recording of Core Patient Information Using Certified EHR (demographics, problem list, medications, allergies).
24/7 Access ("On Call" Service)
Designated Care Team Member
Comprehensive Care Management • Systematic needs assessment (medical and psychosocial). • Ensure receipt of preventive services. • Medication reconciliation, management and oversight of self-management.
Comprehensive Electronic Care Plan • Plan is available timely within and outside the practice (can include fax). • Copy of care plan to patient/caregiver (format not prescribed). • Establish, implement, revise or monitor the plan.
Management of Care Transitions/Referrals (e.g., discharges, ED visit follow up, referrals). • Create/exchange continuity of care document(s) timely (format not prescribed).
Home- and Community-Based Care Coordination • Coordinate with any home- and community-based clinical service providers, and document communication with them regarding psychosocial needs and functional deficits.
Enhanced Communication Opportunities • Offer asynchronous non-face-to-face methods other than telephone, such as secure email.

*All elements that are medically reasonable and necessary must be furnished during the month, but all elements do not necessarily apply every month. Consent need only be obtained once, and initiating visits are only for new patients or patients not seen within a year prior to initiation of CCM.

Early data show that, in general, CCM services are increasing patient and practitioner satisfaction, saving costs and enabling solo practitioners to remain in independent practice.[82] Utilization has reached approximately 75 percent of the level we initially assumed under the PFS when we began paying for CCM services separately under the PFS. While these are positive results, we believe that CCM services (especially complex CCM services) continue to be underutilized. In addition, we note that, at the February 2019 CPT Editorial Panel meeting, certain specialty associations requested refinements to the existing CCM codes, and consideration of their proposal was postponed. Also, we have heard from some stakeholders suggesting that the time increments for non-complex CCM performed by clinical staff should be changed to recognize finer increments of time, and that certain requirements related to care planning are unclear. Based on our consideration of this ongoing feedback, we believe some of the refinements requested by specialty associations and other stakeholders may be necessary to improve payment accuracy, reduce unnecessary burden

[82] *https://innovation.cms.gov/Files/reports/chronic-care-mngmt-finalevalrpt.pdf.*

and help ensure that beneficiaries who need CCM services have access to them. Accordingly, we proposed the following changes to the CCM code set for CY 2020.

a. Non-Complex CCM Services by Clinical Staff (CPT Code 99490, HCPCS Codes GCCC1 and GCCC2)

Currently, the clinical staff CPT code for non-complex CCM, CPT code 99490 *(Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.)* describes 20 or more minutes of clinical staff time spent performing chronic care management activities under the direction of a physician/qualified health care professional (QHP). When we initially adopted this code for payment and, in feedback we have since received, a number of stakeholders suggested that CMS undervalued the PE RVU because we assumed that the minimum time for the code (20 minutes of clinical staff time) would be typical (see, for example, 79 FR 67717 through 67718). In the CY 2017 PFS final rule with comment period, we continued to consider whether the payment amount for CPT code 99490 is appropriate, given the amount of time typically spent furnishing CCM services (81 FR 80243 through 80244). We adopted the complex CCM codes for payment beginning in CY 2017, in part, to pay more appropriately for services furnished to beneficiaries requiring longer service times (see below). Some stakeholders continue to recommend that we should create an add-on code for non-complex CCM performed by clinical staff, such that these services would be defined and valued in 20-minute increments of time with additional payment for each additional 20 minutes of clinical staff time spent performing care management activities.

We agreed that coding changes that identify additional time increments may improve payment accuracy for non-complex CCM. Accordingly, we proposed to adopt two new G codes with new increments of clinical staff time instead of the existing single CPT code (CPT code 99490). The first G code would have described the initial 20 minutes of clinical staff time, and the second G code would have described each additional 20 minutes thereafter. We intended these would be temporary G codes, to be used for PFS payment instead of CPT code 99490 until the CPT Editorial Panel can consider revisions to the current CPT code set. We said we would consider adopting any CPT code(s) once the CPT Editorial Panel completes its work. We acknowledged that imposing a transitional period during which G codes would be used under the PFS in lieu of the CPT codes is potentially disruptive, and solicited comment on whether the benefit of proceeding with the proposed G codes outweighs the burden of transitioning to their use in the intervening year(s) before a decision by the CPT Editorial Panel.

We proposed that the base code would be HCPCS code GCCC1 *(Chronic care management services, initial 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; and comprehensive care plan established, implemented, revised, or monitored. (Chronic care management services of less than 20 minutes duration, in a calendar month, are not reported separately))*. We proposed a work RVU of 0.61 for HCPCS code GCCC1, which we crosswalked from CPT code 99490. We believed these codes would have a similar amount of work since they would have the same intra-service time of 15 minutes.

We proposed an add-on HCPCS code GCCC2 *(Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Use GCCC2 in conjunction with GCCC1). (Do not report GCCC1, GCCC2 in the same calendar month as GCCC3, GCCC4, 99491))*. We proposed a work RVU of 0.54 for HCPCS code GCCC2 based on a crosswalk to CPT code 11107 (*Incisional biopsy of skin (e.g., wedge) (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)*), which has a work RVU of 0.54, which we believed would accurately reflect the work associated with each additional 20 minutes of CCM services. Both codes would have the same intraservice time of 15 minutes. We noted that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, codes need not share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. In this case, we believed CPT code 11107 shared a similar work intensity to proposed HCPCS code GCCC2. Furthermore, although HCPCS codes GCCC1 and GCCC2 would share the same intraservice time, add-on codes may have lower intensity than the base codes because they describe the continuation of an already initiated service.

We solicited public comment on whether we should limit the number of times HCPCS code GCCC2 could be reported in a given service period for a given beneficiary. It was not clear how often more than 40 minutes of clinical staff time is currently spent or is medically necessary. In addition, once 60 minutes of clinical staff time is spent, many or most patients might also require complex medical decision-making, and such patients would already be described under existing coding for complex CCM. We believed a limit (such as allowing the add-on code to be reported only once per service period per beneficiary) may be appropriate in order to maintain distinctions between complex and non-complex CCM, as well as appropriately limit beneficiary cost sharing and program spending to medically necessary services. We noted that complex CCM already describes (in part) 60 or more minutes of clinical staff time in a service period. We solicited comment on whether and how often beneficiaries who do not require complex CCM (for example, do not require the complex medical decision making that is part of complex CCM) would need 60 or more minutes of non-complex CCM clinical staff time and thereby warrant more than one use of HCPCS code GCCC2 within a service period.

Comment: Several commenters supported the proposed add-on HCPCS code GCCC2, and recommended that there be a limit on its use (frequency) to keep non-complex CCM distinct from complex CCM. These commenters stated that patients requiring multiple uses of the add-on service likely require the moderate to high medical decision making of complex CCM. Other commenters stated that, while they have patients who do not require the complex

medical decision making that is part of complex CCM, care management for these patients is time-consuming and would require 60 or more minutes of non-complex CCM clinical staff time within a service period. These commenters suggested that limiting the frequency of reporting HCPCS code GCCC2 to twice during a service period allows for accurate payments, while preventing inappropriate use of the code. The Medicare Payment Advisory Commission (MedPAC) expressed support for the proposed add-on code for non-complex CCM because it would better reflect the resources involved in furnishing care management services and increase payment accuracy for CCM. Other commenters stated that G codes would help to facilitate earlier implementation and would ease transition to any updates made to CPT codes.

However, a number of commenters were not supportive of the introduction of temporary G codes within the CCM code set, believing it would produce administrative burden and cause confusion. These commenters stated that in September 2019 the CPT Editorial Panel was considering an application for similar changes to refine the code set. These commenters urged us to work with the CPT Editorial Panel regarding changes to the CCM code set and its revaluation. A few commenters suggested that CMS could achieve its burden reduction goals by continuing to recognize CPT codes 99490, 99487, and 99489 and also provide CMS-specific guidance for those codes for purposes of billing Medicare.

Response: We are not finalizing our proposal to create HCPCS codes GCCC1 (or GCCC3 or GCCC4, see below) in consideration of commenters' concerns that the introduction of temporary G codes replacing most of the CCM code set would create administrative burden, especially in light of the CPT Editorial Panel's currently ongoing work in this area. However we are finalizing GCCC2 (the add-on for non-complex CCM clinical staff time), henceforth referred to as G2058, because this code addresses what we believe is an important gap in the current code set that should be addressed more immediately, and that finalizing only this single G code rather than the full range of proposed G codes will allow payment for these services while creating significantly less administrative burden. Practitioners who choose to use G2058 can report the initial 20 minutes of non-complex CCM under CPT code 99490 and receive increased payment for their work under G2058. We are sympathetic to commenters' concerns that the introduction of temporary replacement G codes across the CCM code set may introduce substantial confusion or administrative burden, but we believe a single new G code to pay more for additional 20-minute increments of non-complex CCM clinical staff time is important to pursue now. We are finalizing the work RVU for G2058 as proposed.

We agree with commenters that there should be a frequency limit on the reporting of HCPCS code G2058 to maintain the distinction between complex and non-complex CCM and, in response to comments, we are finalizing that HCPCS code G2058 will be reportable a maximum of two times within a given service period for a given beneficiary. We believe the availability of this G code will further our policy goals to improve payment accuracy for care management services and allow practitioners and their teams to spend more time with their patients.

Comment: A few commenters suggested that CMS should revalue the work RVUs for the CCM codes given that we proposed to increase the work RVUs for TCM, and CCM was originally valued based upon the RVUs for TCM.

Response: We appreciate these suggestions but, given the ongoing work of the CPT Editorial Panel regarding these codes, we will consider potential revaluation of this code set in the context of any future changes or recommendations that may be made by the CPT Editorial Panel or the RUC.

b. Complex CCM Services (CPT Codes 99487 and 99489, and HCPCS Codes GCCC3 and GCCC4)

There are two CPT codes for complex CCM:

- CPT code 99487 *(Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately);* and
- CPT code 99489 *(each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure).*

Complex CCM describes care management for patients who require not only more clinical staff time, but also complex medical decision-making and establishment or substantial revision of the care plan. Specifically, the CPT codes for complex CCM include in the code descriptors a requirement for establishment or substantial revision of the comprehensive care plan. The code descriptors for complex CCM also include moderate to high complexity medical decision-making (moderate to high complexity medical decision-making is an explicit part of the services).

We proposed to adopt two new G codes that would be used for billing under the PFS instead of CPT codes 99487 and 99489, and that would not include the service component of substantial care plan revision. We believed it is not necessary to explicitly include substantial care plan revision because patients requiring moderate to high complexity medical decision making implicitly need and receive substantial care plan revision. The service component of substantial care plan revision is potentially duplicative with the medical decision making service component and, therefore, we believed it is unnecessary as a means of distinguishing eligible patients. Instead of CPT code 99487, we proposed to adopt HCPCS code GCCC3 *(Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately)).* We proposed a work RVU of 1.00 for HCPCS code GCCC3, which is a crosswalk to CPT code 99487.

Instead of CPT code 99489, we proposed to adopt HCPCS code GCCC4 *(each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Report GCCC4 in conjunction with GCCC3). (Do not report GCCC4 for care*

management services of less than 30 minutes additional to the first 60 minutes of complex chronic care management services during a calendar month)). We proposed a work RVU of 0.50 for HCPCS code GCCC4, which is a crosswalk to CPT code 99489.

We intended these would be temporary G codes to remain in place until the CPT Editorial Panel can consider revising the current code descriptors for complex CCM services. We stated that we would consider adopting any new or revised complex CCM CPT code(s) once the CPT Editorial Panel completes its work. We acknowledged that imposing a transitional period during which G codes would be used under the PFS in lieu of the CPT codes is potentially disruptive. We solicited comment on whether the benefit of proceeding with the proposed G codes outweighs the burden of transitioning to their use in the intervening year(s) before a decision by the CPT Editorial Panel.

Comment: While expressing general support for the proposed changes to these codes to remove the element of substantial care plan revision, several commenters expressed concerns that the temporary introduction of G codes would produce administrative burden and cause confusion. These commenters stated that in September 2019 the CPT Editorial Panel was considering an application for similar changes to refine the code set and clarify care planning. These commenters urged us to work with the CPT Editorial Panel regarding changes to the CCM code set and its revaluation. However, other commenters stated that G codes would help to facilitate earlier implementation and would ease transition to any updates made to CPT codes. A few commenters suggested that CMS could achieve its burden reduction goals by continuing to recognize CPT codes 99490, 99487, and 99489 and also provide CMS-specific guidance for those codes for purposes of billing Medicare.

Response: We are not finalizing our proposal to create HCPCS codes GCCC3 and GCCC4 in light of concerns raised by commenters, especially in light of the CPT Editorial Panel's currently ongoing work in this area and the concerns expressed by those that we expect would likely provide these services. Instead, given the support for our proposed care planning changes, for CY 2020 we will continue to recognize CPT codes 99487 and 99489, but with a different care planning element for purposes of billing Medicare. Beginning in CY 2020, for PFS billing purposes for CPT codes 99487 and 99489, we will interpret the code descriptor ''establishment or substantial revision of a comprehensive care plan'' to mean that a comprehensive care plan is established, implemented, revised, or monitored. This will allow for consistency in the care planning service element of complex CCM and non-complex CCM services provided by clinical staff. While we usually create G codes with alternative code descriptors when our payment policy varies from what is included in a CPT code descriptor(s), the change we proposed for the complex CCM care plan code descriptor is a relatively minor modification to the CPT code descriptor that we believe can be accomplished without the use of G codes. We look forward to reviewing any refinements or other recommendations for these services that may come from the CPT Editorial Panel and the RUC, and will consider such recommendations through our rulemaking process.

c. Typical Care Plan

In 2013, in working with the physician community to develop and propose the CCM codes for PFS payment, the medical community recommended and CMS agreed that adequate care planning is integral to managing patients with multiple chronic conditions. We stated our belief that furnishing care management to beneficiaries with multiple chronic conditions requires complex and multidisciplinary care modalities that involve, among other things, regular physician development and/or revision of care plans and integration of new information into the care plan (78 FR 43337). In the CY 2014 PFS final rule with comment period (78 FR 74416 through 74418), consistent with recommendations CMS received in 2013 from the AMA's Complex Chronic Care Coordination Workgroup, we finalized a CCM scope of service element for a patient-centered plan of care with the following characteristics: It is a comprehensive plan of care for all health problems and typically includes, but is not limited to, the following elements: Problem list; expected outcome and prognosis; measurable treatment goals; cognitive and functional assessment; symptom management; planned interventions; medical management; environmental evaluation; caregiver assessment; community/social services ordered; how the services of agencies and specialists unconnected to the practice will be directed/coordinated; identify the individuals responsible for each intervention, requirements for periodic review; and when applicable, revisions of the care plan.

The CPT Editorial Panel also incorporated and adopted this language in the prefatory language for Care Management Services codes (page 49 of the 2019 CPT Codebook) including CCM services.

As we continue to consider the need for potential refinements to the CCM code set, we have heard that there is still some confusion in the medical community regarding what a care plan typically includes. We re-reviewed this language for CCM, and we believe there may be aspects of the typical care plan language we adopted for CCM that are redundant or potentially unduly burdensome. In our CY 2020 PFS proposed rule, we noted that because these are ''typical'' care plan elements, these elements do not comprise a set of strict requirements that must be included in a care plan for purposes of billing for CCM services; the elements are intended to reflect those that are typically, but perhaps not always, included in a care plan as medically appropriate for a particular beneficiary. Nevertheless, we proposed to eliminate the phrase ''community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention'' and insert the phrase ''interaction and coordination with outside resources and practitioners and providers.'' We believed simpler language could describe the important work of interacting and coordinating with resources external to the practice. While it is preferable, when feasible, to identify who is responsible for interventions, it may be difficult to maintain an up-to-date listing of responsible individuals especially when they are outside of the practice, for example, when there is staff turnover or assignment changes.

We proposed new language to read: The comprehensive care plan for all health issues typically includes, but is not limited to, the following elements:

- Problem list.
- Expected outcome and prognosis.
- Measurable treatment goals.
- Cognitive and functional assessment.
- Symptom management
- Planned interventions.
- Medical management.
- Environmental evaluation
- Caregiver assessment
- Interaction and coordination with outside resources and practitioners and providers.
- Requirements for periodic review.
- When applicable, revision of the care plan.

We welcomed feedback on our proposal, including language that would best guide practitioners as they decide what to include in their comprehensive care plan for CCM recipients.

Comment: Commenters largely supported CMS' proposed definition of the typical care plan, and stated that it was simpler than the current definition and also comprehensive.

Response: We thank the commenters for their support and are finalizing our proposed changes to the typical care plan for all CCM. We are eliminating the phrase ''community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention'' and inserting the phrase ''interaction and coordination with outside resources and practitioners and providers.'' The new language will read: ''The comprehensive care plan for all health issues typically includes, but is not limited to, the following elements:

- Problem list.
- Expected outcome and prognosis.
- Measurable treatment goals.
- Cognitive and functional assessment.
- Symptom management
- Planned interventions.
- Medical management.
- Environmental evaluation
- Caregiver assessment
- Interaction and coordination with outside resources and practitioners and providers.
- Requirements for periodic review.
- When applicable, revision of the care plan.''

We anticipate that this change will reduce burden and simplify the important work of interacting and coordinating with resources external to the practice.

4. Principal Care Management (PCM) Services

A gap we identified in coding and payment for care management services is care management for patients with only one chronic condition. The current CCM codes require patients to have two or more chronic conditions. These codes are primarily billed by practitioners who are managing a patient's total care over a month, including primary care practitioners and some specialists such as cardiologists or nephrologists. We have heard from a number of stakeholders, especially those in specialties that use the office/outpatient E/M code set to report the majority of their services, that there can be significant resources involved in care management for a single high risk disease or complex chronic condition that is not well accounted for in existing coding (FR 78 74415). This issue has also been raised by the stakeholder community in proposal submissions to the Physician-Focused Payment Model Technical Advisory Committee (PTAC), which are available at *https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee.* Therefore, we proposed separate coding and payment for Principal Care Management (PCM) services, which describe care management services for one serious chronic condition. A qualifying condition will typically be expected to last between 3 months and 1 year, or until the death of the patient, may have led to a recent hospitalization, and/or place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

Although we did not propose any restrictions on the specialties that could bill for PCM, we expect that most of these services will be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. We expect that, in most instances, initiation of PCM will be triggered by an exacerbation of the patient's complex chronic condition or recent hospitalization such that disease-specific care management is warranted. We anticipate that in the majority of instances, PCM services will be billed when a single condition is of such complexity that it cannot be managed as effectively in the primary care setting, and instead requires management by another, more specialized, practitioner. For example, a typical patient may present to their primary care practitioner with an exacerbation of an existing chronic condition. Although the primary care practitioner may be able to provide care management services for this one complex chronic condition, it is also possible that the primary care practitioner and/or the patient could instead decide that another clinician should provide relevant care management services. In this case, the primary care practitioner will still oversee the overall care for the patient while the practitioner billing for PCM services will provide care management services for the specific complex chronic condition. The treating clinician may need to provide a disease-specific care plan or may need to make frequent adjustments to the patient's medication regimen. The expected outcome of PCM is for the patient's condition to be stabilized by the treating clinician so that overall care management for the patient's condition can be returned to the patient's primary care practitioner. If the beneficiary only has one complex chronic condition that is overseen by the primary care practitioner, then the primary care practitioner will also be able to bill for PCM services. We proposed that PCM services include coordination of medical and/or psychosocial care related to the single complex chronic condition, provided by a physician or clinical staff under the direction of a physician or other qualified health care professional.

We anticipate that many patients will have more than one complex chronic condition. If a clinician is providing PCM services for one complex chronic condition, management of the patient's other conditions will continue to be managed by the primary care practitioner while the patient is receiving PCM services for a single complex condition. It is also possible that the patient could receive PCM services from more than one clinician if the patient experiences an exacerbation of more than one complex chronic condition simultaneously.

For CY 2020, we proposed to make separate payment for PCM services via two new G codes: HCPCS code G2064 *(Comprehensive care management services for a single high-risk disease, e.g., Principal Care Management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities)* and HCPCS code G2065 *(Comprehensive care management for a single high-risk disease services, e.g., Principal Care Management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the*

medication regimen, and/or the management of the condition is unusually complex due to comorbidities). HCPCS code G2064 would be reported when, during the calendar month, at least 30 minutes of physician or other qualified health care provider time is spent on comprehensive care management for a single high risk disease or complex chronic condition. HCPCS code G2065 would be reported when, during the calendar month, at least 30 minutes of clinical staff time is spent on comprehensive management for a single high risk disease or complex chronic condition.

For HCPCS code G2064, we proposed a crosswalk to the work value associated with CPT code 99217 *(Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital* ''*observation status*'' *if the discharge is on other than the initial date of* ''*observation status.*'' *To report services to a patient designated as* ''*observation status*'' *or* ''*inpatient status*'' *and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234–99236 as appropriate]))* as we believe these values most accurately reflect the resource costs associated when the billing practitioner performs PCM services. CPT code 99217 has the same intraservice time as HCPCS code G2064 and the physician work is of similar intensity. Therefore, we proposed a work RVU of 1.28 for HCPCS code G2064.

For HCPCS code G2065, we proposed a crosswalk to the work and PE inputs associated with CPT code 99490 (clinical staff non-complex CCM) as we believe these values reflect the resource costs associated with the clinician's direction of clinical staff who are performing the PCM services, and the intraservice times and intensity of the work for the two codes will be the same. Therefore, we proposed a work RVU of 0.61 for HCPCS code G2065.

Although we proposed separate coding and payment for PCM services performed by clinical staff with the oversight of the billing professional and services furnished directly by the billing professional, we solicited comment on whether both codes are necessary to appropriately describe and bill for PCM services. We note that we are basing this coding structure on the codes for CCM services with CPT code 99491 reflecting care management by the billing professional and CPT code 99490 reflecting care management by clinical staff directed by a physician or other qualified health care professional.

We acknowledged that we concurrently proposed revisions for both complex and non-complex CCM services. Were we not to finalize the changes for both complex and non-complex CCM services, we stated our belief that the overall structure and description of the CCM services remain close enough to serve as a model for the coding structure and description of services for the proposed PCM services. We solicited public comment on whether it would be appropriate to create an add-on code for additional time spent each month (similar to HCPCS code GCCC2 discussed above) when PCM services are furnished by clinical staff under the direction of the billing practitioner.

Comment: Most commenters supported separate payment for PCM services, noting the gap in payment for care management and coordination for a patient's single complex or chronic condition. Other commenters were supportive of the policy goal but expressed concerns that the work described by PCM is duplicative of work being furnished as part of CCM and encouraged CMS to work with the CPT editorial panel to develop coding for this service.

Response: We appreciate the support for both the policy goal of appropriate payment for care management services conducted for a patient's single complex or chronic condition and for separate payment for PCM services. We look forward to reviewing and considering recommendations from the CPT Editorial Panel and the RUC, should they develop and value CPT codes describing this or similar services, through our rulemaking process.

Comment: A few commenters stated that HCPCS code G2064 was undervalued and should have a work RVU of 1.45, which is the same work RVU as CPT code 99491 (*Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored*). CPT code 99491 describes the work associated with care management performed by the billing practitioner, in contrast to CPT code 99490, which describes the work associated with supervision of care management performed by clinical staff. Commenters pointed out that CPT codes 99491 and 99490 served as the model for HCPCS codes G2064 and G2065. Commenters stated that CPT code 99491 was a more accurate crosswalk for HCPCS code G2064 because both codes describe the work associated with care management and coordination performed by the billing practitioner, and G2065 describes the work associated with supervising care management done by clinical staff and was valued the same as CPT code 99490. Commenters also pointed out that, although PCM services describe care management associated with a single condition, the fact that this condition has most likely experienced an exacerbation or has caused the patient to recently be hospitalized, results in greater intensity than the work associated with managing multiple chronic conditions, some of which may be more stable.

Response: After considering these comments, we agree that the work RVU we proposed for code G2064 (1.28 RVUs) should be valued through a crosswalk to CPT code 99491, and we agree with the points made by commenters regarding the intensity of care management for a single condition, especially when that condition has likely experienced an exacerbation. We also agree that the relativity between CPT codes 99490 and 99491 should be preserved in HCPCS codes G2064 and G2065. Therefore, we are finalizing an RVU of 1.45 for HCPCS code G2064.

Comment: A few commenters supported creation of an add-on code for additional time spent engaged in PCM services beyond the initial 30 minutes, similar to HCPCS code G2060 discussed above.

Response: We thank commenters for their input. Given that this is a new service, we believe it would be more appropriate to monitor uptake and stakeholder response, and we will consider whether to establish a separate add-on code for additional time spent furnishing PCM services beyond the initial 30 minutes for possible future rulemaking.

Although we believe that PCM services describe a situation where a patient's condition is severe enough to require care management for a single complex chronic condition beyond what is described by CCM or performed in the primary care setting, we are concerned that a possible unintended consequence of making separate payment for care management for a single chronic condition is that a patient with multiple

chronic conditions could have their care managed by multiple practitioners, each only billing for PCM, which could potentially result in fragmented patient care, overlaps in services, and duplicative services. Although we did not propose additional requirements for the PCM services, we did consider alternatives such as requiring that the practitioner billing PCM must document ongoing communication with the patient's primary care practitioner to demonstrate that there is continuity of care between the specialist and primary care settings, or requiring that the patient have had a face-to-face visit with the practitioner billing PCM within the prior 30 days to demonstrate that they have an ongoing relationship. We solicited comment on whether requirements such as these are necessary or appropriate, and whether there should be additional requirements to prevent potential care fragmentation or service duplication.

We received public comments on whether requirements such as these are necessary or appropriate, and whether there should be additional requirements to prevent potential care fragmentation or service duplication. The following is a summary of the comments we received and our responses.

Comment: Many commenters' shared CMS' concerns. Some commenters recommended that CMS not finalize separate payment for PCM services, stating that this would move away from patient-specific, continuous, comprehensive value based care management and coordination toward a more disease specific care management, resulting in fragmented care and service duplication. A few commenters with concerns about care fragmentation suggested that CMS first implement PCM through a demonstration. Others supported requiring the billing practitioner document ongoing communication and care coordination with any other practitioners overseeing care of the patient, such as primary care practitioners, pharmacists, hospitalists, or social workers, as applicable. These commenters stated that this would be sufficient to maintain coordination and continuity of care in the instance where multiple practitioners are involved in furnishing care to the beneficiary. A few commenters also suggested that CMS not allow billing of PCM services by multiple practitioners for the same indication. Still other commenters stated that it was not necessary to include any requirements pertaining to care fragmentation or service duplication, and that such requirements would be a barrier to uptake.

Response: While we share commenters' concerns regarding care fragmentation and service duplication, we do not believe they rise to the level that separate payment should not be adopted for these services. The type of care management services that we believe are appropriately described by the PCM codes involve work intensively focused on managing a single condition and, with very few exceptions, could not be replaced by a single practitioner billing CCM services for management of multiple chronic conditions. However, we also believe it necessary to put in place some requirements so as to avoid a situation where each of a patient's individual conditions are being managed separately by different practitioners who all bill for PCM services. Therefore, we are finalizing a requirement that ongoing communication and care coordination between all practitioners furnishing care to the beneficiary must be documented by the practitioner billing for PCM in the patient's medical record.

Due to the similarity between the description of the PCM and CCM services, both of which involve non-face-to-face care management services, we proposed that the full CCM scope of service requirements apply to PCM, including documenting the patient's verbal consent in the medical record. We solicited comment on whether there are required elements of CCM services that the public and stakeholders believe should not be applicable to PCM, and should be removed or altered.

A high level summary of these requirements is available in Table 23 and available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf.* Both the initiating visit and the patient's verbal consent are necessary as not all patients who meet the criteria to receive separately billable PCM services may want to receive these services. The beneficiary should be educated as to what PCM services are and any cost sharing that may apply. Additionally, as practitioners have informed us that beneficiary cost sharing is a significant barrier to provision of other care management services, we solicited comment on how best to educate practitioners and beneficiaries on the benefits of PCM services.

TABLE 23: Chronic Care Management Services Summary

CCM Service Summary*
Verbal Consent • Inform regarding availability of the service; that only one practitioner can bill per month; the right to stop services effective at the end of any service period; and that cost sharing applies (if no supplemental insurance). • Document that consent was obtained.
Initiating Visit for New Patients (separately paid)
Certified Electronic Health Record (EHR) Use • Structured Recording of Core Patient Information Using Certified EHR (demographics, problem list, medications, allergies).
24/7 Access ("On Call" Service)
Designated Care Team Member
Comprehensive Care Management • Systematic needs assessment (medical and psychosocial). • Ensure receipt of preventive services. • Medication reconciliation, management and oversight of self-management.
Comprehensive Electronic Care Plan • Plan is available timely within and outside the practice (can include fax). • Copy of care plan to patient/caregiver (format not prescribed). • Establish, implement, revise or monitor the plan.
Management of Care Transitions/Referrals (e.g., discharges, ED visit follow up, referrals). • Create/exchange continuity of care document(s) timely (format not prescribed).
Home- and Community-Based Care Coordination • Coordinate with any home- and community-based clinical service providers, and document communication with them regarding psychosocial needs and functional deficits.
Enhanced Communication Opportunities • Offer asynchronous non-face-to-face methods other than telephone, such as secure email.

*All elements that are medically reasonable and necessary must be furnished during the month, but all elements do not necessarily apply every month. Consent need only be obtained once, and initiating visits are only for new patients or patients not seen within a year prior to initiation of CCM.

We received public comments on whether there are required elements of CCM services that the public and stakeholders believe should not be applicable to PCM, and should be removed or altered. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported application of the required elements of CCM to PCM with a number of refinements, although a few urged CMS not to add overly burdensome billing requirements. Commenters requested that CMS clarify that elements of CCM, such as the ''systematic needs assessment,'' ''receipt of preventive services,'' and a ''comprehensive care plan'' must be furnished only for the specific chronic condition for which the billing practitioner is treating the patient. Some commenters pointed out that a ''comprehensive care plan'' was not needed when a practitioner is engaged in care management and coordination of a single complex or chronic condition, and instead suggested it be changed to ''disease-specific care plan.'' Other commenters suggest that we remove this language entirely. Commenters expressed concern with requiring that the EHR be certified to a particular standard. Commenters generally recommended that an initiating visit be furnished within a window of time to demonstrate that a relationship has been established between the beneficiary and the practitioner furnishing PCM. Commenters supported the retention of the requirement that there be the capacity for in-person care management. Commenters also recommended that verbal and or written consent be documented in the medical record so that the patient is aware of the service and any applicable cost sharing, although some stated that this was a burdensome requirement given that they may not know in advance which beneficiaries will require PCM services.

Response: We thank commenters for all their input. We agree with commenters that a ''disease-specific'' care plan is more appropriate than a comprehensive care plan, as the practitioner will be providing care coordination and management for a single condition, and as such, the care plan may be more limited. We also agree that certain aspects of CCM, such as ''systematic needs assessment'' and ''receipt of preventive services'' should only be furnished as applicable to the condition being treated and should not be a requirement to bill for PCM services. Table 24 shows the elements of CCM, as revised in response to comments, that will be required for PCM.

TABLE 24: Principal Care Management Services Summary

PCM Service Summary*
Verbal Consent • Inform regarding availability of the service; that only one practitioner can bill per month; the right to stop services effective at the end of any service period; and that cost sharing applies (if no supplemental insurance). • Document that consent was obtained.
Initiating Visit for New Patients (separately paid)
Certified Electronic Health Record (EHR) Use • Structured Recording of Core Patient Information Using EHR (demographics, problem list, medications, allergies).
24/7 Access ("On Call" Service)
Designated Care Team Member
Disease Specific Care Management Disease Specific Care Management may include, as applicable: • Systematic needs assessment (medical and psychosocial). • Ensure receipt of preventive services. • Medication reconciliation, management and oversight of self-management.
Disease Specific Electronic Care Plan • Plan is available timely within and outside the practice (can include fax). • Copy of care plan to patient/caregiver (format not prescribed). • Establish, implement, revise or monitor the plan.
Management of Care Transitions/Referrals (e.g., discharges, ED visit follow up, referrals, as applicable). • Create/exchange continuity of care document(s) timely (format not prescribed).
Home- and Community-Based Care Coordination • Coordinate with any home- and community-based clinical service providers, and document communication with them regarding psychosocial needs and functional deficits, as applicable.
Enhanced Communication Opportunities • Offer asynchronous non-face-to-face methods other than telephone, such as secure email.

*All elements that are medically reasonable and necessary must be furnished during the month, but all elements do not necessarily apply every month. Consent need only be obtained once, and initiating visits are only for new patients or patients not seen within a year prior to initiation of PCM.

With regard to the certified EHR, we continue to believe that use of certified EHR technology is vital to ensure that practitioners are capable of providing the full scope of PCM services, such as timely care coordination and continuity of care (see our prior discussion of this issue at 79 FR 67723). The use of certified EHR technology helps ensure that members of the care team have timely access to the patient's most updated health information. Also, we believe that use of certified EHR technology among physicians and other practitioners will increase as we move forward to implement the Quality Payment Program, including MIPS and Advanced Alternative Payment Models, as well as other value-based payment initiatives. Accordingly, we are not modifying the proposed use of certified EHR technology as an element of PCM services.

We received public comments on how best to educate practitioners and beneficiaries on the benefits of PCM services. The following is a summary of the comments we received and our responses.

Comment: Commenters recommended that CMS issue guidance for billing and coding criteria, clinical situations in which PCM may be billed, and what defines a complex condition.

Response: We look forward to continued engagement with the public to revise and refine PCM services as they are implemented. We encourage stakeholders to submit questions and information to CMS so that we might consider changes or clarification for future rulemaking.

Additionally, we proposed to add HCPCS code G2065 to the list of designated care management services for which we allow general supervision as described in our regulation at § 410.26(b)(5).

Comment: Commenters supported adding HCPCS code G2065 to the list of designated care management services for which we allow general supervision.

Response: We thank commenters for their support and are finalizing as proposed.

Due to the potential for duplicative payment, we proposed that PCM could not be billed by the same practitioner for the same patient concurrent with certain other care management services, such as CCM, behavioral health integration services, and monthly capitated ESRD payments. We also proposed that PCM will not be billable by the same practitioner for the same patient during a surgical global period, as we believe those resource costs will already be included in the valuation of the global surgical code.

We also solicited comment on any potential for duplicative payment between the PCM services and other services, such as interprofessional consultation services (CPT codes 99446–99449 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional*), CPT code 99451 (*Interprofessional telephone/*

internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time), and CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes*) or remote patient monitoring (CPT code 99091 *(Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days),* CPT code 99453 *(Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment),* and CPT code 99457 *(Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month).*

Comment: Commenters generally supported restricting the number of care management services billable by the same practitioner for the same patient, stating that this was necessary to avoid service duplication. A few commenters also stated that services such as interprofessional consultation and chronic care RPM should not be separately billable in the same month as PCM by the same practitioner for the same beneficiary. Others disagreed, stating the RPM and interprofessional consultations describe distinct services not accounted for in the work of PCM. RPM in particular was described by these commenters as being complimentary to PCM services, rather than duplicative.

Commenters requested clarification as to potential overlap between PCM and CCM and some commenters suggested that PCM could be billed concurrent with CCM for the same beneficiary, if billed by different practitioners. Commenters also requested that CMS clarify any potential overlap between PCM and HCPCS code GPC1X (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).*

Response: We do not believe there will be a duplication of care management between PCM and other care management services solely as a result of separate payment for the new PCM codes, particularly with the revised list of required elements which better distinguish PCM services from CCM. However, we also agree with commenters that PCM services should not be furnished with other care management services by the same practitioner for the same beneficiary, nor should PCM services be furnished at the same time as interprofessional consultations for the same condition by the same practitioner for the same patient. However, we are convinced by stakeholders who stated that RPM services are distinct from PCM and could be billed concurrently by the same practitioner for the same beneficiary provided that the time is not counted twice. We will also be monitoring billing of these services. We will appreciate continued input and engagement on these issues with the public and stakeholder community, and may make refinements to these policies in future rulemaking.

With regard to the relationship between PCM services and HCPCS code GPC1X, we do not believe there is any overlap. We note that PCM describes ongoing care management services and is billed monthly, whereas HCPCS code GPC1X is an adjustment to an office/outpatient E/M visit (which are separately billable alongside PCM) to capture additional resource costs associated with performing either a primary care visit or a visit that is part of ongoing care of a patients single, serious, or complex condition.

Comment: A commenter requested that RHCs and FQHCs be allowed to furnish and report PCM services.

Response: We thank the commenter for the suggestion. While we did not propose a new mechanism for RHCs and FQHCs to report PCM services specifically, we recognize that the requirements for the new PCM codes are similar to the requirements for the services described by HCPCS code G0511, which is the RHC/FQHC-specific general care management code, and will consider adding PCM to G0511 in future rulemaking.

5. Chronic Care Remote Physiologic Monitoring Services

Chronic care remote physiologic monitoring (RPM) services involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan, and the managing of a patient under the treatment plan. The current CPT code 99457 is a treatment management code, billable after 20 minutes or more of clinical staff/physician/other qualified professional time with a patient in a calendar month.

In September 2018, the CPT Editorial Panel revised the CPT code structure for CPT code 99457 effective beginning CY 2020. The new code structure retains CPT code 99457 as a base code that describes the first 20 minutes of the treatment management services, and uses a new add-on code to describe subsequent 20 minute intervals of the service. The new code descriptors for CY 2020 are: CPT code 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; initial 20 minutes*) and CPT code 99458 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes*).

In considering the work RVUs for the new add-on CPT code 99458, we first considered the value of its base code. We previously valued the base code at 0.61 work RVUs. Given the value of the base code, we did not agree with the RUC-recommended work RVU of 0.61 for CPT code 99458. Instead, we proposed a work RVU of 0.50 for the add-on code, which we believed was supported by CPT code 88381 (*Microdissection (i.e., sample preparation of microscopically identified target); manual*) and which has the same intraservice and total times of 20 minutes with an XXX global period and work RVU of 0.53, as well as the survey value at the 25th percentile. We proposed the RUC-recommended direct PE inputs for CPT code 99458.

Finally, we proposed that RPM services could be furnished under general supervision. Because care management services include establishing, implementing, revising, or monitoring treatment plans, as well as providing support services, and because

RPM services include establishing, implementing, revising, and monitoring a specific treatment plan for a patient related to one or more chronic conditions that are monitored remotely, we believed that CPT codes 99457 and 99458 should be included as designated care management services. Designated care management services can be furnished under general supervision. Section 410.26(b)(5) of our regulations states that designated care management services can be furnished under the general supervision of the ''physician or other qualified health care professional (who is qualified by education, training, licensure/regulation and facility privileging)'' (see also 2019 CPT Codebook, page xii) when these services or supplies are provided incident to the services of a physician or other qualified healthcare professional. The physician or other qualified healthcare professional supervising the auxiliary personnel need not be the same individual treating the patient more broadly. However, only the supervising physician or other qualified healthcare professional may bill Medicare for incident to services.

We received public comments on the proposed valuation of the RPM add-on CPT code 99458 and our proposal to designate CPT codes 99457 and 99458 as care management services. The following is a summary of the comments we received in response to our two proposals, as well as our responses.

Comment: We received numerous comments regarding our valuation of the new RPM code, CPT code 99458. Commenters uniformly disagreed with our proposed work RVU of 0.50 writing that there are no efficiencies to be gained when continuing the same treatment management service for an additional 20 minutes. Some commenters questioned our use of CPT code 88381 (*Microdissection (i.e., sample preparation of microscopically identified target); manual*) as a reference code, a code that does not resemble the work and the intensity of the work furnished during a care management session.

Response: We thank the many commenters for their insights into the work required for CPT codes 99457 and 99458.

Comment: Commenters uniformly agreed with our proposal to designate CPT codes 99457 and 99458 as care management services so that the services can be furnished under general supervision.

Response: We agree with commenters that the add-on code requires the same work time and intensity as the RPM base code. Therefore, we are finalizing the RUC-recommended work RVU 0.61 for CPT code 99458. We are also finalizing the RUC-recommended direct PE. In addition, we are finalizing our proposal to designate both CPT code 99457 and CPT code 99458 care management codes as defined in § 410.26(b)(5) of our regulations.

Comment: Several commenters expressed concerns about the ambiguity of the code descriptors for the RPM codes. Commenters requested that CMS define what is meant by ''physiologic parameters'', ''digitally transmitted data'' (as opposed to patient-reported data), ''medical device,'' and ''interactive communication''. Several commenters asked if we could expand the list of practitioners allowed to furnish RPM services, while others requested that we clarify who can furnish and bill for the RPM services. One commenter stated that the prefatory language for the codes should state explicitly that an established patient-practitioner relationship must exist prior to billing for RPM services. Another commenter recommended that we provide guidance related to billing and documentation for RPM. Some commenters questioned whether the codes could be used for patients that without chronic conditions.

Response: We appreciate the many questions raised by commenters about the set of RPM codes and understand the frustration commenters expressed with the current code descriptors. Therefore, given the numerous questions raised by commenters, we plan to consider these and other questions related to RPM in future rulemaking.

Comment: We received a few comments asking whether RPM is a billable service in RHCs and FQHCs.

Response: RHCs are paid an all-inclusive rate (AIR) when a medically necessary, face-to-face visit is furnished by an RHC practitioner. FQHCs are paid the lesser of their charges or the FQHC PPS rate when a medically-necessary, face-to-face visit is furnished by an FQHC practitioner. Both the RHC AIR and the FQHC PPS rate include all services and supplies furnished incident to the visit. Services such as RPM are not separately billable because they are already included in the RHC AIR or FQHC PPS payment.

6. Comment Solicitation on Consent for Communication Technology-Based Services

In the CY 2019 PFS final rule, we finalized separate payment for a number of services that could be furnished via telecommunications technology. Specifically, we finalized HCPCS code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*)), HCPCS code G2012 (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*)), CPT codes 99446–99449 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional*), CPT code 99451 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time*), and CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes*).

As discussed in that rule, (83 FR 59490 through 59491), while a few commenters suggested that it would be less burdensome to obtain a general consent for multiple services at once, we stipulated that verbal consent must be documented in the medical record for each service furnished so that the beneficiary is aware of any applicable cost sharing. This is similar to the requirements for other non-face-to-face care management services under the PFS.

We have continued to hear from stakeholders that requiring advance beneficiary consent for each of these services is burdensome. For HCPCS codes G2010 and G2012, stakeholders have stated that it is difficult and burdensome to obtain consent at the outset of each of what are meant to be brief check-in services. For CPT codes 99446–99449, 99451 and 99452, practitioners have informed us that it is

particularly difficult for the consulting practitioner to obtain consent from a patient they have never seen. Given our longstanding goals to reduce burden and promote the use of communication technology-based services (CTBS), we sought comment in the CY 2020 PFS proposed rule on whether a single advance beneficiary consent could be obtained for a number of communication technology-based services. During the consent process, the practitioner will make sure the beneficiary is aware that utilization of these services will result in a cost sharing obligation. We solicited comment on the appropriate interval of time or number of services for which consent could be obtained, for example, for all these services furnished within a 6-month or 1-year period, or for a set number of services, after which a new consent will need to be obtained. We also solicited comment on the potential program integrity concerns associated with allowing advance consent and how best to minimize those concerns.

We received public comments on the appropriate interval of time or number of services for which consent could be obtained and the potential program integrity concerns associated with allowing advance consent and how best to minimize those concerns. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported requiring a generalized consent for multiple communication technology-based services or interprofessional consultations. Most commenters suggested that a year was an appropriate interval for which consent should be obtained, although some commenters suggested other time intervals, such as every 6 months, quarterly, or no requirement at all.

A few commenters suggested that there should be separate consent processes for services that involve an interaction with the patient, such as HCPCS codes G2010 to report the remote evaluation of recorded video and/or images for an established patient and G2012 to report brief communication technology-based service for an established patient, and services that do not involve direct interaction with the patient, such as CPT codes 99446 through 99449, 99451 and 99452, which describe services such as electronic assessment and management by a consultative physician.

Other commenters raised more general concerns with beneficiary cost sharing, pointing out that beneficiaries may not be accustomed to being charged cost sharing for non-face-to-face services. These commenters urged CMS to eliminate cost sharing for these services.

Response: We appreciate commenters' support for allowing a single consent to be obtained for multiple CTBS or interprofessional consultation services over an interval of time, rather than requiring consent to be obtained prior to each service. Given the commenters' support, we are finalizing a policy to permit a single consent to be obtained for multiple CTBS or interprofessional consultation services. Based on feedback from commenters, we believe an appropriate interval for the single consent is one year, and we are finalizing that the single consent must be obtained at least annually. We will continue to consider whether a separate consent should be obtained for services that involve direct interaction between the patient and practitioner, and those that do not involve interaction such as interprofessional services; and we may address this issue in potential future rulemaking.

We also appreciate commenters' continued concerns about the burden associated with cost sharing for CTBS and interprofessional consultation services. Although we do not have statutory authority to eliminate cost sharing for these services, we appreciate the continued input from the public as to how best to educate both practitioners and beneficiaries to reduce instances of unexpected bills.

7. Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

RHCs and FQHCs are paid for general care management services using HCPCS code G0511, which is an RHC and FQHC-specific G-code for 20 minutes or more of CCM services, complex CCM services, CCM furnished by a physician or other qualified health care professional, or general behavioral health services, and we are allowing G0511 to also be billed when the requirements for PCM are met. Payment for this service is set at the average of the national, non-facility payment rates for CPT codes 99490, 99487, 99491, and 99484. We proposed to use the non-facility payment rates for HCPCS codes GCCC1 and GCCC3 instead of the non-facility payment rates for CPT codes 99490 and 99487, respectively, if these changes were finalized for practitioners billing under the PFS; as indicated above, these codes were not finalized. We note that we did not propose any changes in the valuation of these codes.

Comment: Regarding the use HCPCS codes GCCC1 and GCCC3, commenters noted they would be supportive of this change if they were finalized for practitioners billing under the PFS for RHCs and FQHCs.

Response: Since HCPCS codes GCCC1 and GCCC3 are not being finalized for use under the PFS, we are not finalizing this change for RHCs and FQHCs. Therefore, payment for HCPCS G0511 will continue to set based on the average of the national, non-facility payment rates for CPT codes 99490, 99487, 99491, and 99484.

L. Coinsurance for Colorectal Cancer Screening Tests

Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and, under sections 1861(pp)(1)(B) and (C) of the Act, ''screening flexible sigmoidoscopy'' and ''screening colonoscopy'' are two of the recognized procedures. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to include other tests or procedures in the definition, and modifications to the tests and procedures described under this subsection, ''with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.'' Section 1861(s)(2)(R) of the Act includes these colorectal cancer screening tests in the definition of the medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(ddd)(3) of the Act includes these colorectal cancer screening services within the definition of ''preventive services.'' In addition, section 1833(a)(1)(Y) of the Act provides for payment for preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B under the PFS at 100 percent of the lesser of the actual charge or the fee schedule amount for these colorectal cancer screening tests, and under the OPPS at 100 percent of the OPPS payment amount. As such, there is no beneficiary responsibility for coinsurance for recommended colorectal cancer screening tests as defined in section 1861(pp)(1) of the Act.

Under these statutory provisions, we have issued regulations governing payment for colorectal cancer screening tests at 42 CFR 410.152(l)(5). We pay 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance.

In addition to screening tests, which typically are furnished to patients in the absence of signs or symptoms of illness

or injury, Medicare also covers various diagnostic tests (§ 410.32). In general, diagnostic tests must be ordered by the physician or practitioner who is treating the beneficiary, and who uses the results of the diagnostic test in the management of the patient's specific medical problem. Under Part B, Medicare may cover flexible sigmoidoscopies and colonoscopies as diagnostic tests when those tests are reasonable and necessary as specified in section 1862(a)(1)(A) of the Act. When these services are furnished as diagnostic tests rather than as screening tests, patients are responsible for the Part B coinsurance (normally 20 percent) associated with these services.

We define ''colorectal cancer screening tests'' in our regulation at § 410.37(a)(1) to include ''flexible screening sigmoidoscopies'' and ''screening colonoscopies, including anesthesia furnished in conjunction with the service.'' Under our current policies, we exclude from the definition of colorectal screening services colonoscopies and sigmoidoscopies that begin as a screening service, but where a polyp or other growth is found and removed as part of the procedure. The exclusion of these services from the definition of colorectal cancer screening services is based upon separate provisions of the statute dealing with the detection of lesions or growths during procedures (62 FR 59048, 59082, October 31, 1997). Section 1834(d)(2)(D) of the Act provides that if, during the course of a screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. Similarly, section 1834(d)(3)(D) of the Act that provides if, during the course of a screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

Because we interpret sections 1834(d)(2)(C)(ii) and 1834(d)(3)(C)(ii) of the Act to require us to pay for these tests as diagnostic tests, rather than as screening tests, the 100 percent payment rate for recommended preventive services under section 1833(a)(1)(Y) of the Act, as codified in our regulation at § 410.152(l)(5), would not apply to those diagnostic procedures. As such, beneficiaries are responsible for the usual coinsurance that applies to the services (20 or 25 percent of the cost of the services depending on the setting).

Under section 1833(b) of the Act, before making payment under Medicare Part B for expenses incurred by a beneficiary for covered Part B services, beneficiaries must first meet the applicable deductible for the year. Section 4104 of the Affordable Care Act (that is, the Patient Protection and Affordable Care Act (Pub L. 111–148, enacted March 23, 2010), and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010), collectively referred to as the ''Affordable Care Act'') amended section 1833(b)(1) of the Act to make the deductible inapplicable to expenses incurred for certain preventive services that are recommended with a grade of A or B by the USPSTF, including colorectal cancer screening tests as defined in section 1861(pp) of the Act. Section 4104 of the Affordable Care Act also added a sentence at the end of section 1833(b)(1) of the Act specifying that the exception to the deductible shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. Although the Affordable Care Act addressed the applicability of the deductible in the case of a colorectal cancer screening test that involves biopsy or tissue removal, it did not alter the coinsurance provision in section 1833(a) of the Act for such procedures. Although public commenters encouraged the agency to also eliminate the coinsurance in these circumstances, the agency found that the statute did not provide for elimination of the coinsurance (75 FR 73170, 73431, November 29, 2010).

Beneficiaries have continued to contact us noting their ''surprise'' that a coinsurance (20 or 25 percent depending on the setting) applies when they expected to receive a colorectal screening procedure to which coinsurance does not apply, but instead received what Medicare considers to be a diagnostic procedure because polyps were discovered and removed. Similarly, physicians have also expressed concerns about the reactions of beneficiaries when they are informed that they will be responsible for coinsurance if polyps are discovered and removed during what they expected to be a screening procedure to which coinsurance does not apply. Other stakeholders and some members of Congress have regularly expressed to us that they consider the agency's policy on coinsurance for colorectal screening procedures during which tissue is removed to be a misinterpretation of the law.

Over the years, we have released a wide variety of publicly available educational materials that explain the Medicare preventive services benefits as part of our overall outreach activities to Medicare beneficiaries. These materials contain a complete description of the Medicare preventive services benefits, including information on colorectal cancer screening, and also provide relevant details on the applicability of cost sharing. These materials are available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1243319.html.* We believe that the information in these materials can be instrumental in continuing to educate physicians and beneficiaries about cost sharing obligations in order to mitigate instances of ''surprise'' billing. In the CY 2020 PFS proposed rule (84 FR 40556), we solicited comment on whether we should consider establishing a requirement that the physician who plans to furnish a colorectal cancer screening notify the patient in advance that a screening procedure could result in a diagnostic procedure if polyps are discovered and removed, and that coinsurance may apply. Specifically, we solicited comment on whether we should require the physician, or their staff, to provide a verbal notice with a notation in the medical record, or whether we should consider a different approach to informing patients of the copay implications, such as a written notice with standard language that we would require the physician, or their staff, to provide to patients prior to a colorectal cancer screening. We also solicited comment on what mechanism, if any, we should consider using to monitor compliance with a notification requirement if we decide to finalize one for CY 2020 or through future rulemaking.

We received over 1,600 public comments on the requirements for coinsurance for colorectal cancer screening tests.

Comment: Many comments were on coverage and statutory issues, such as coverage for colorectal cancer screening more frequently and not requiring coinsurance for diagnostic colonoscopy.

Response: These comments are out of scope.

Comment: Many commenters were on professionals providing information to individuals receiving a screening colonoscopies. Several commenters noted that Medicare could do a better job of educating beneficiaries about when screening colonoscopies become diagnostic colonoscopies, and therefore, coinsurance applies. In addition to not understanding that when removal of a polyp, lesion or growth is discovered a screening colonoscopy becomes a diagnostic one, some commenters misunderstood that a screening colonoscopy can only occur every 10 years for most individuals, or the appropriate frequency for a high risk individual. Many commenters were confused that a diagnostic colonoscopy occurs after a positive Cologuard® or fetal occult blood tests rather than a screening colonoscopy.

Response: As a result of our review of the public comments, we intend to undertake a comprehensive review of all of our outreach materials, such as the Medicare & You Handbook and Medicare Preventive Services, to see if Medicare policies on payment and coverage for screening colonoscopies can be made clearer. We believe this would be a service to Medicare beneficiaries.

M. Therapy Services

1. Repeal of the Therapy Caps and Limitation To Ensure Appropriate Therapy

a. Background

In the CY 2019 PFS proposed and final rules (83 FR 34850; 83 FR 59654 and 59661), we discussed the statutory requirements of section 50202 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018). Beginning January 1, 2018, section 50202 of the BBA of 2018 repealed the Medicare outpatient therapy caps and the therapy cap exceptions process, while retaining the cap amounts as limitations and requiring medical review to ensure that therapy services are furnished when appropriate. Section 50202 of the BBA of 2018 amended section 1833(g) of the Act by adding a new paragraph (7)(A) requiring that after expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the previous therapy cap amounts, all therapy suppliers and providers must continue to use an appropriate modifier on claims. We implemented this provision by continuing to require use of the existing KX modifier. By using the KX modifier on the claim, the therapy supplier or provider is attesting that the services are medically necessary and that supportive justification is documented in the medical record. As with the incurred expenses for the prior therapy cap amounts, there is one amount for physical therapy (PT) and speech language pathology (SLP) services combined, and a separate amount for occupational therapy (OT) services. These KX modifier threshold amounts are indexed annually by the Medicare Economic Index (MEI). After the beneficiary's incurred expenditures for outpatient therapy services exceed the KX modifier threshold amount for the year, claims for outpatient therapy services without the KX modifier are denied.

Section 50202 of the BBA of 2018 also added a new paragraph 7(B) to section 1833(g) of the Act which retained the targeted medical review (MR) process for 2018 and subsequent years, but established a lower threshold amount of $3,000 rather than the $3,700 threshold amount that had applied for the original manual MR process established by section 3005(g) of the Middle Class Tax Relief and Jobs Creation Act of 2012 (MCTRJCA) (Pub. L. 112–96, February 22, 2012). The manual MR process with a threshold amount of $3,700 was replaced by the targeted MR process with the same threshold amount through amendments made by section 202 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015).

With the latest amendments made by the BBA of 2018, for CY 2018 (and each successive calendar year until 2028, at which time it is indexed annually by the MEI), the MR threshold is $3,000 for PT and SLP services and $3,000 for OT services. For purposes of applying the targeted MR process, we use a criteria-based process for selecting providers and suppliers that includes factors such as a high percentage of patients receiving therapy beyond the medical review threshold as compared to peers. For information on the targeted medical review process, please visit *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html.*

In the CY 2019 PFS final rule (83 FR 59661), when discussing our tracking and accrual process for outpatient therapy services in the section on the KX Threshold Amounts, we noted that we track each beneficiary's incurred expenses for therapy services annually by applying the PFS-based payment amount for each service less any applicable multiple procedure reduction for CMS-designated ''always therapy'' services. We also stated that we use the PFS rates to accrue expenses for therapy services provided in critical access hospitals (CAHs) as required by section 1833(g)(6)(B) of the Act, added by section 603(b) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, January 2, 2013). As discussed below, we mistakenly indicated that this statutory requirement was extended by subsequent legislation, including section 50202 of the BBA of 2018.

b. Summary of Proposed Regulatory Revisions

While we explained and implemented the changes required by section 50202 of the BBA of 2018 in CY 2019 PFS rulemaking (83 FR 34850; 83 FR 59654 and 59661), we did not codify those changes in regulation text. In the CY 2020 PFS proposed rule, we proposed to revise the regulations at §§ 410.59 (outpatient occupational therapy) and 410.60 (physical therapy and speech-language pathology) to incorporate the changes made by section 50202 of the BBA of 2018. Specifically, we proposed to add a new paragraph (e)(1)(v) to §§ 410.59 and 410.60 to clarify that the specified amounts of annual per-beneficiary incurred expenses are no longer applied as limitations but as threshold amounts above which services require, as a condition of payment, inclusion of the KX modifier; and that use of the KX modifier confirms that the services are medically necessary as justified by appropriate documentation in the patient's medical record. We proposed to amend paragraph (e)(2) in §§ 410.59 and 410.60 to specify the therapy services and amounts that are accrued for purposes of applying the KX modifier threshold, including the continued accrual of therapy services furnished by CAHs directly or under arrangements at the PFS-based payment rates. We also proposed to amend paragraph (e)(3) in §§ 410.59 and 410.60 for the purpose of applying the medical review threshold to clarify the threshold amounts and the applicable years for both the manual MR process originally established through section 3005(g) of MCTRJCA and the targeted MR process established by the MACRA, and including the changes made through section 50202 of the BBA of 2018 as discussed previously.

In the CY 2019 PFS final rule (83 FR 59661), we incorrectly stated that section 1833(g)(6)(B) of the Act continues to require that we accrue expenses for therapy services furnished by CAHs at the PFS rate because the provision, originally added by section 603(b) of the ATRA, was extended by subsequent legislation, including section 50202 of the BBA of 2018. The

requirement in section 1833(g)(6)(B) of the Act was actually time-limited to services furnished in CY 2013. To apply the therapy caps (and now the KX modifier thresholds) after the expiration of the requirement in 1833(g)(6)(B) of the Act, we needed a process to accrue the annual expenses for therapy services furnished by CAHs and, in the CY 2014 PFS final rule with comment period, we elected to continue the process prescribed in section 1833(g)(6)(B) of the Act (78 FR 74405 through 74410).

We received public comments on the proposed revisions to regulation text to codify the changes required by section 50202 of the BBA of 2018. The following is a summary of the comments we received and our responses.

Comment: Several commenters appreciated our proposal to clarify and codify the requirements as outlined in section 50202 of the BBA of 2018.

Response: We thank commenters for their support.

After considering the comments, we are finalizing as proposed the changes in regulation text to reflect the requirements of section 50202 of the BBA of 2018.

2. Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

a. Background

Section 53107 of the BBA of 2018 added a new subsection 1834(v) to the Act to require in paragraph (1) that, for services furnished on or after January 1, 2022, payment for outpatient physical and occupational therapy services for which payment is made under sections 1848 or 1834(k) of the Act which are furnished in whole or in part by a therapy assistant must be paid at 85 percent of the amount that is otherwise applicable. Section 1834(v)(2) of the Act further required that we establish a modifier to identify these services by January 1, 2019, and that claims for outpatient therapy services furnished in whole or in part by a therapy assistant must include the modifier effective for dates of service beginning on January 1, 2020. Section 1834(v)(3) of the Act required that we implement the subsection through notice and comment rulemaking.

In the CY 2019 PFS proposed and final rules (83 FR 35850 through 35852 and 83 FR 59654 through 50660, respectively), we established two modifiers—one to identify services furnished in whole or in part by a physical therapist assistant (PTA) and the other to identify services furnished in whole or in part by an occupational therapy assistant (OTA). The modifiers are defined as follows:

- *CQ Modifier:* Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant.
- *CO Modifier:* Outpatient occupational therapy services furnished in whole or in part by an occupational therapy assistant.

In the CY 2019 PFS final rule, we clarified that the CQ and CO modifiers are required to be used when applicable for services furnished on or after January 1, 2020, on the claim line of the service alongside the respective GP or GO therapy modifier to identify services furnished under a PT or OT plan of care. The GP and GO therapy modifiers, along with the GN modifier for speech-language pathology (SLP) services, have been used since 1998 to track and accrue the per-beneficiary incurred expenses amounts to different therapy caps, now KX modifier thresholds, one amount for PT and SLP services combined and a separate amount for OT services. We also clarified in the CY 2019 PFS final rule that the CQ and CO modifiers will trigger application of the reduced payment rate for outpatient therapy services furnished in whole or in part by a PTA or OTA, beginning for services furnished in CY 2022.

In response to public comments on the CY 2019 PFS proposed rule, we did not finalize our proposed definition of ''furnished in whole or in part by a PTA or OTA'' as a service for which any minute of a therapeutic service is furnished by a PTA or OTA. Instead, we finalized a *de minimis* standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA.

We also explained in the CY 2019 PFS proposed and final rules (83 FR 35850 through 35852 and 83 FR 59654 through 59660, respectively) that the CQ and CO modifiers would not apply to claims for outpatient therapy services that are furnished by, or incident to the services of, physicians or nonphysician practitioners (NPPs) including nurse practitioners, physician assistants, and clinical nurse specialists. This is because our regulations for outpatient physical and occupational therapy services require that an individual furnishing outpatient therapy services incident to the services of a physician or NPP must meet the qualifications and standards for a therapist. As such, only therapists and not therapy assistants can furnish outpatient therapy services incident to the services of a physician or NPP (83 FR 59655 through 59656); and, the new PTA and OTA modifiers cannot be used on the line of service of the professional claim when the rendering NPI identified on the claim is a physician or an NPP. We also intend to revise our manual provisions at Pub. 100–02, Medicare Benefit Policy Manual (MBPM), Chapter 15, section 230, as appropriate, to reflect requirements for the new CQ and CO modifiers that will be used to identify services furnished in whole or in part by a PTA or OTA starting in CY 2020. We anticipate amending these manual provisions for CY 2020 to reflect the policies we adopt through the CY 2020 PFS notice and comment rulemaking process.

In PFS rulemaking for CY 2019, we identified certain situations when the therapy assistant modifiers do apply. The modifiers are applicable to:

- Therapeutic portions of outpatient therapy services furnished by PTAs/OTAs, as opposed to administrative or other non-therapeutic services that can be performed by others without the education and training of OTAs and PTAs.
- Services wholly furnished by PTAs or OTAs without physical or occupational therapists.
- Evaluative services that are furnished in part by PTAs/OTAs (keeping in mind that PTAs/OTAs are not recognized to wholly furnish PT and OT evaluation or re-evaluations).

We also identified some situations when the therapy assistant modifiers do not apply. They do not apply when:

- PTAs/OTAs furnish services that can be done by a technician or aide who does not have the training and education of a PTA/OTA.
- Therapists exclusively furnish services without the involvement of PTAs/OTAs.

Finally, we noted that we would be further addressing application of the modifiers for therapy assistant services and the 10 percent *de minimis* standard more specifically in PFS rulemaking for CY 2020, including how the modifiers are applied in different scenarios for different types of services.

b. Applying the CQ and CO Modifiers

We interpreted the references in section 1834(v)(1) and (2) of the Act to outpatient physical therapy ''service'' and outpatient occupational therapy ''service'' to mean a specific procedure code that describes a PT or OT service. This interpretation makes sense because section 1834(v)(2) of the Act requires the use of a modifier to identify on each request for payment, or bill submitted for an outpatient therapy service furnished in whole or in part by a PTA/OTA. For purposes of billing, each outpatient therapy service is identified by a procedure code.

To apply the *de minimis* standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA, we proposed to make the 10 percent calculation based on the respective therapeutic minutes of time spent by the therapist and the PTA/OTA, rounded to the nearest whole minute. The minutes of time spent by a PTA/OTA furnishing a therapeutic service can overlap partially or completely with the time spent by a physical or occupational therapist furnishing the service. We proposed that the total time for a service would be the total time spent by the therapist (whether independent of, or concurrent with, a PTA/OTA) plus any additional time spent by the PTA/OTA independently furnishing the therapeutic service. When deciding whether the therapy assistant modifiers apply, we proposed that if the PTA/OTA participates in the service concurrently with the therapist for only a portion of the total time that the therapist delivers a service, the CQ/CO modifiers apply when the minutes furnished by the therapy assistant are greater than 10 percent of the total minutes spent by the therapist furnishing the service. If the PTA/OTA and the therapist each separately furnish portions of the same service, we proposed that the CQ/CO modifiers would apply when the minutes furnished by the therapy assistant are greater than 10 percent of the total minutes—the sum of the minutes spent by the therapist and therapy assistant—for that service. We proposed to apply the CQ/CO modifier policies to all services that would be billed with the respective GP or GO therapy modifier. We believed this was appropriate because it is the same way that CMS currently identifies physical therapy or occupational therapy services for purposes of accruing incurred expenses for the thresholds and targeted review process.

For purposes of deciding whether the 10 percent *de minimis* standard is exceeded, we offered two different ways to compute this. The first is to divide the PTA/OTA minutes by the total minutes for the service—which is (a) the therapist's total time when PTA/OTA minutes are furnished concurrently with the therapist, or (b) the sum of the PTA/OTA and therapist minutes when the PTA/OTA's services are furnished separately from the therapist; and then to multiply this number by 100 to calculate the percentage of the service that involves the PTA/OTA. We proposed to round to the nearest whole number so that when this percentage is 11 percent or greater, the 10 percent *de minimis* standard is exceeded and the CQ/CO modifier is applied. The other method is simply to divide the total time for the service (as described above) by 10 to identify the 10 percent *de minimis* standard, and then to add one minute to identify the number of minutes of service by the PTA/OTA that would be needed to exceed the 10 percent standard. For example, where the total time of a service is 60 minutes, the 10 percent standard is six (6) minutes, and adding one minute yields seven (7) minutes. Once the PTA/OTA furnishes at least 7 minutes of the service, the CQ/CO modifier would be required to be added to the claim for that service. As noted above, we proposed to round the minutes and percentages of the service to the nearest whole integer. For example, when the total time for the service is 45 minutes, the 10 percent calculation would be 4.5 which would be rounded up to 5, and the PTA/OTA's contribution would need to meet or exceed 6 minutes before the CQ/CO modifier is required to be reported on the claim. See Table 25 for minutes needed to meet or exceed using the ''simple'' method with typical times for the total time of a therapy service.

TABLE 25: Simple Method for Determining When CQ/CO Modifiers Apply

METHOD TWO: Simple Method to apply 10 Percent *De Minimis* Standard			
Total Time* Examples Using Typical Service Total Times	Determine the 10 percent standard by dividing service Total Time by 10	Round 10 Percent standard to Next Whole Integer	PTA/OTA Minutes Needed to Exceed -- Apply CQ/CO
10	1.0	1.0	2.0
15	1.5	2.0	3.0
20	2.0	2.0	3.0
30	3.0	3.0	4.0
45	4.5	5.0	6.0
60	6.0	6.0	7.0
75	7.5	8.0	9.0

Total Time equals total therapist minutes plus any PTA/OTA independent minutes. Concurrent minutes: When PTA/OTA's minutes are furnished concurrently with the therapist, total time equals the total minutes of the therapist's service. Separate minutes: When PTA/OTA's minutes are furnished separately from the minutes furnished by the therapist, total time equals the sum of the minutes of the service furnished by the PT/OT plus the minutes of the service furnished separately by the PTA/OTA.

We also clarified that the 10 percent *de minimis* standard, and therefore, the CQ/CO modifiers are not applicable to services in which the PTA/OTA did not participate. To the extent that the PTA/OTA and the physical therapist/occupational therapist (PT/OT) separately furnish different services that are described by procedure codes defined in 15-minute increments, billing examples and proposed policies are included below in Scenario Two.

We proposed to address more specifically the application of the 10 percent *de minimis* standard in various clinical scenarios to decide when the CQ/CO modifiers apply. We acknowledged that application of the 10 percent *de minimis* standard can work differently depending on the types of services and scenarios involving both

the PTA/OTA and the PT/OT. Therapy services are typically furnished in multiple units of the same or different services on a given treatment day, which can include untimed services (not billable in multiple units) and timed services that are defined by codes described in 15-minute intervals. The majority of the untimed services that therapists bill for fall into three categories: (1) Evaluative procedures, (2) group therapy, and (3) supervised modalities. We discuss each of these in greater detail below. Only one (1) unit can be reported in the claim field labeled ''units'' for each procedure code representing an untimed service. The preponderance of therapy services, though, are billed using codes that are described in 15-minute increments. These services are typically furnished to a patient on a single day in multiple units of the same and/or different services. Under our current policy, the total number of units of one or more timed services that can be added to a claim depends on the total time for all the 15-minute timed codes that were delivered to a patient on a single date of service. A summary of our proposals for applying the CQ/CO modifiers using the 10 percent *de minimis* standard, along with applicable billing scenarios, are outlined below by category. In each of these scenarios, we assumed that the PTA/OTA minutes are for therapeutic services.

• *Evaluations and re-evaluations: CPT codes 97161 through 97163 for physical therapy evaluations for low, moderate, and high complexity level, and CPT code 97164 for physical therapy re-evaluation; and CPT codes 97165 through 97167 for occupational therapy evaluations for low, moderate, and high complexity level, and CPT 97168 for occupational therapy re-evaluation.* These PT and OT evaluative procedures are untimed codes and cannot be billed in multiple units—one unit is billed on the claim. As discussed in CY 2019 PFS rulemaking (83 FR 35852 and 83 FR 59656) and noted above, PTAs/OTAs are not recognized to furnish evaluative or assessment services, but to the extent that they furnish a portion of an evaluation or re-evaluation (such as completing clinical labor tasks for each code) that exceeds the 10 percent *de minimis* standard, the appropriate therapy assistant modifier (CQ or CO) must be used on the claim. We note that it is possible for the PTA/OTA to furnish these minutes either concurrently or separately from the therapist. For example, when the PTA/OTA assists the PT/OT concurrently for a 5-minute portion of the 30 minutes that a PT or OT spent furnishing an evaluation (for example, CPT code 97162 for moderate complexity PT evaluation or CPT code 97165 for a low complexity OT evaluation—each have a typical therapist face-to-face time of 30 minutes), the respective CQ or CO modifier is applied to the service because the 5 minutes surpasses the 10 percent *de minimis* standard. In other words, 10 percent of 30 minutes is 3 minutes, and the CQ or CO modifier applies if the PTA/OTA furnishes more than 3 minutes, meaning at least 4 minutes, of the service. If the PTA/OTA separately furnishes a portion of the service that takes 5 minutes (for example, performing clinical labor tasks such as obtaining vital signs, providing self-assessment tool to the patient and verifying its completion), and then the PT/OT separately (without the PTA/OTA) furnishes a 30 minute face-to-face evaluative procedure—bringing the total time of the service to 35 minutes (the sum of the separate PTA/OTA minutes, that is, 5 minutes, plus the 30-minute therapist service), the CQ or CO modifier would be applied to the service because the 5 minutes of OTA/PTA time exceeds 10 percent of the 35 total minutes for the service. In other words, 10 percent of 35 minutes is 3.5 minutes which is rounded up to 4 minutes. The CQ or CO modifier would apply when the PTA/OTA furnishes 5 or more minutes of the service, as discussed above and referenced in Table 25.

• *Group Therapy: CPT code 97150 (requires constant attendance of therapist or assistant, or both).* CPT code 97150 describes a service furnished to a group of 2 or more patients. Like evaluative services, this code is an untimed service and cannot be billed in multiple units on the claim, so one unit of the service is billed for each patient in the group. For the group service, the CQ/CO modifier would apply when the PTA/OTA wholly furnishes the service without the therapist. The CQ/CO modifier would also apply when the total minutes of the service furnished by the PTA/OTA (whether concurrently with, or separately from, the therapist), exceed 10 percent of the total time, in minutes, of the group therapy service (that is, the total minutes of service spent by the therapist (with or without the PTA/OTA) plus any minutes spent by the PTA/OTA separately from the therapist). For example, the modifiers would apply when the PTA/OTA participates concurrently with the therapist for 5 minutes of a total group therapy service time of 40-minutes (based on the time of the therapist); or when the PTA/OTA separately furnishes 5 minutes of a total group time of 40 minutes (based on the sum of minutes of the PTA/OTA (5) and therapist (35)).

• *Supervised Modalities: CPT codes 97010 through 97028, and HCPCS codes G0281, G0183, and G0329.* Modalities, in general, are physical agents that are applied to body tissue in order to produce a therapeutic change through various forms of energy, including but not limited to thermal, acoustic, light, mechanical or electric. Supervised modalities, for example vasopneumatic devices, paraffin bath, and electrical stimulation (unattended), do not require the constant attendance of the therapist or supervised therapy assistant, unlike the modalities defined in 15-minute increments that are discussed in the below category. When a supervised modality, such as whirlpool (CPT code 97022), is provided without the direct contact of a PT/OT and/or PTA/OTA, that is, it is furnished entirely by a technician or aide, the service is not covered and cannot be billed to Medicare. Supervised modality services are untimed, so only one unit of the service can be billed regardless of the number of body areas that are treated. For example, when paraffin bath treatment is provided to both of the patient's hands, one unit of CPT code 97018 can be billed, not two. For supervised modalities, the CQ or CO modifier would apply to the service when the PTA/OTA fully furnishes all the minutes of the service, or when the minutes provided by the PTA or OTA exceed 10 percent of total minutes of the service. For example, the CQ/CO modifiers would apply when either (1) the PTA/OTA concurrently furnishes 2 minutes of a total 8-minute service by the therapist furnishing paraffin bath treatment (HCPCS code 97018) because 2 minutes is greater than 10 percent of 8 minutes ((0.8 minute, or 1 minute after rounding); or (2) the PTA/OTA furnishes 3 minutes of the service separately from the therapist who furnishes 5 minutes of treatment for a total time of 8 minutes (total time equals the sum of the PT/OT minutes plus the separate PTA/OTA minutes) because 3 minutes is greater than 10 percent of 8 total minutes (0.8 minute rounded to 1 minute).

• *Services defined by 15-minute increments/units: These timed codes are included in the following current CPT code ranges: CPT codes 97032 through 97542—including the subset of codes for modalities in the series CPT codes 97032 through 97036; and, codes for procedures in the series CPT codes 97110–97542; CPT codes 97750–97755*

for tests and measurements; and CPT codes: 97760–97763 for orthotic management and training and prosthetic training. Based on CPT instructions for these codes, the therapist (or their supervised therapy assistant, as appropriate) is required to furnish the service directly in a one-on-one encounter with the patient, meaning they are treating only one patient during that time. Examples of modalities requiring one-on-one patient contact include electrical stimulation (attended), CPT code 97032, and ultrasound, CPT code 97035. Examples of procedures include therapeutic exercise, CPT code 97110, neuromuscular reeducation, CPT 97112, and gait training, CPT code 97116.

Our policy for reporting of service units with HCPCS codes for both untimed services and timed services (that is, only those therapy services defined in 15-minute increments) is explained in section 20.2 of Chapter 5 of the Medicare Claims Processing Manual (MCPM). To bill for services described by the timed codes (hereafter, those codes described per each 15-minutes) furnished to a patient on a date of service, the therapist or therapy assistant needs to first identify all timed services furnished to a patient on that day, and then total all the minutes of all those timed codes. Next, the therapist or therapy assistant needs to identify the total number of units of timed codes that can be reported on the claim for the physical or occupational therapy services for a patient in one treatment day. Once the number of billable units is identified, the therapist or therapy assistant assigns the appropriate number of unit(s) to each timed service code according to the total time spent furnishing each service. For example, to bill for one 15-minute unit of a timed code, the qualified professional (the therapist or therapy assistant) must furnish at least 8 minutes and up to 22 minutes of the service; to bill for 2 units, at least 23 minutes and up to 37 minutes, and to bill for 3 units, at least 38 minutes and up to 52 minutes. We note that these minute ranges are applicable when one service, or multiple services, defined by timed codes are furnished by the qualified professional on a treatment day. We understand that the therapy industry often refers to these billing conventions as the ''eight-minute rule.'' The idea is that when a therapist or therapy provider bills for one or more units of services that are described by timed codes, the therapist's direct, one-on-one patient contact time would average 15 minutes per unit. This idea is also the basis for the work values we have established for these timed codes. Our current policies for billing of timed codes and related documentation do not take into consideration whether a service is furnished ''in whole or in part'' by a PTA/OTA, or otherwise address the application of the CQ/CO modifier when the 10 percent *de minimis* standard is exceeded, for those services in which both the PTA/OTA and the PT/OT work together to furnish a service or services.

To support the number of 15-minute timed units billed on a claim for each treatment day, we require that the total timed-code treatment time be documented in the medical record, and that the treatment note must document each timed service, whether or not it is billed, because the unbilled timed service(s) can impact billing. The minutes that each service is furnished can be, but are not required to be, documented. We also require that each untimed service be documented in the treatment note in order to support these services billed on the claim; and, that the total treatment time for each treatment day be documented—including minutes spent providing services represented by the timed codes (the total timed-code treatment time) and the untimed codes. To minimize burden, we are not proposing changes to these documentation requirements in this proposed rule.

Beginning January 1, 2020, in order to provide support for application of the CQ/CO modifier(s) to the claim as required by section 1834(v)(2)(B) of the Act and our regulations at §§ 410.59(a)(4) and 410.60(a)(4), we proposed to add a requirement that the treatment notes explain, via a short phrase or statement, the application or non-application of the CQ/CO modifier for each service furnished that day. We would include this documentation requirement in subsection in Chapter 15, MBPM, section 220.3.E on treatment notes. Because the CQ/CO modifiers also apply to untimed services, our proposed revision to the documentation requirement for the daily treatment note would extend to those codes and services as well. For example, when PTAs/OTAs assist PTs/OTs to furnish services, the treatment note could state one of the following, as applicable: (a) ''Code 97110: CQ/CO modifier applied − PTA/OTA wholly furnished'' or, (b) ''Code 97150: CQ/CO modifier applied − PTA/OTA minutes = 15%'' or ''Code 97530: CQ/CP modifier not applied − PTA/OTA minutes less than 10% standard.'' For those therapy services furnished exclusively by therapists without the use of PTAs/OTA, the PT/OT could note one of the following: ''CQ/CO modifier NA'', or ''CQ/CO modifier NA − PT/OT fully furnished all services.'' Given that the minutes of service furnished by or with the PTA/OTA and the total time in minutes for each service (timed and untimed) are used to decide whether the CQ/CO modifier is applied to a service, we sought comment on whether it would be appropriate to require documentation of the minutes as part of the CQ/CO modifier explanation as a means to avoid possible additional burden associated with a contractor's medical review process conducted for these services. We solicited comment from therapists and therapy providers about current burden associated with the medical review process based on our current policy that does not require the times for individual services to be documented. Based on comments received, if we were to adopt a policy to include documentation of the PTA/OTA minutes and total time (TT) minutes, the CQ/CO modifier explanation could read similar to the following: ''Code 97162 (TT = 30 minutes): CQ/CO modifier not applied − PTA/OTA minutes (3) did not exceed the 10 percent standard.''

To recap, under our policy, therapists or therapy assistants would apply the therapy assistant modifiers to the timed codes by first following the usual process to identify all procedure codes for the 15-minute timed services furnished to a beneficiary on the date of service, add up all the minutes of the timed codes furnished to the beneficiary on the date of service, decide how many total units of timed services are billable for the beneficiary on the date of service (based on time ranges in the chart in the manual), and assign billable units to each billable procedure code. The therapist or therapy assistant would then need to decide for each billed procedure code whether or not the therapy assistant modifiers apply.

As previously explained, the CQ/CO modifier does not apply if all units of a procedure code were furnished entirely by the therapist; and, where all units of the procedure code were furnished entirely by the PTA/OTA, the appropriate CQ/CO modifier would apply. When some portion of the billed procedure code is furnished by the PTA/OTA, the therapist or therapy assistant would need to look at the total minutes for all the billed units of the service, and compare it to the minutes of the service furnished by the PTA/OTA as described above in order to decide whether the 10 percent *de minimis* standard is exceeded. If the minutes of the service furnished by the

PTA/OTA are more than 10 percent of the total minutes of the service, the therapist or therapy assistant would assign the appropriate CQ or CO modifier. We would make clarifying technical changes to chapter 5, section 20.2 of the MCPM to reflect the policies adopted through in this rulemaking related to the application or non-application of the therapy assistant modifiers. We anticipated that we would add examples to illustrate when the applicable therapy assistant modifiers must be applied, similar to the examples provided below.

In the CY 2020 PFS proposed rule, we provided detailed examples of clinical scenarios to illustrate how the 10 percent *de minimis* standard would be applied under our proposals when therapists and their assistants work together concurrently or separately to treat the same patient on the same day (84 FR 40562 through 40564).

c. Regulatory Provisions

In accordance with section 1834(v)(2)(B) of the Act, we proposed to amend §§ 410.59(a)(4) and 410.60(a)(4) for outpatient physical and occupational therapy services, respectively, and § 410.105(d) for physical and occupational therapy services furnished by comprehensive outpatient rehabilitation facilities (CORFs) as authorized under section 1861(cc) of the Act, to establish as a condition of payment that claims for services furnished in whole or in part by an OTA or PTA must include a prescribed modifier; and that services will not be considered furnished in part by an OTA or PTA unless they exceed 10 percent of the total minutes for that service, beginning for services furnished on and after January 1, 2020. To implement section 1834(v)(1) of the Act, we proposed to amend §§ 410.59(a)(4) and 410.60(a)(4) for outpatient physical and occupational therapy services, respectively, and at § 410.105(d) for physical and occupational therapy services furnished by CORFs to specify that claims from physical and occupational therapists in private practice paid under section 1848 of the Act and from providers paid under section 1834(k) of the Act for physical therapy and occupational therapy services that contain a therapy assistant modifier, are paid at 85 percent of the otherwise applicable payment amount for the service for dates of service on and after January 1, 2022. As specified in the CY 2019 PFS final rule, we also noted that the CQ or CO modifier is to be applied alongside the corresponding GP or GO therapy modifier that is required on each claim line of service for physical therapy or occupational therapy services. Beginning for dates of service and after January 1, 2020, claims missing the corresponding GP or GO therapy modifier will be rejected/returned to the therapist or therapy provider so they can be corrected and resubmitted for processing.

As discussed in the CY 2019 PFS proposed and final rules (*see* 83 FR 35850 and 83 FR 59654), we established that the reduced payment rate under section 1834(v)(1) of the Act for the outpatient therapy services furnished in whole or in part by therapy assistants is not applicable to outpatient therapy services furnished by CAHs, for which payment is made under section 1834(g) of the Act. We clarified that we do not interpret section 1834(v) of the Act to apply to outpatient physical therapy or occupational therapy services furnished by CAHs, or by other providers for which payment for outpatient therapy services is not made under section 1834(k) of the Act based on the PFS rates.

We received almost 9,000 public comments on the proposed payment provisions for outpatient PT and OT services furnished in whole or in part by therapy assistants. The following is a summary of the comments we received and our responses.

Comment: Many commenters objected to our proposal that the time for the therapeutic service furnished ''in part'' by the PTA/OTA that counts towards the 10 percent standard includes both the minutes spent concurrently with and separately from the therapist. These commenters also expressed concerns that this unfairly discounts services that are fully furnished by therapists in which the therapy assistant supports them while providing a service. Some of these commenters stated that section 53107 of the BBA of 2018 does not permit the application of the assistant modifier for a PT or OT service furnished by the respective physical or occupational therapist and that CMS exceeded its authority in proposing to do so.

Many commenters stated that when a therapy assistant and therapist furnish care to a patient at the same time, it is apparent the patient requires both professionals; and, that this clinical scenario either represents a highly skilled procedure or one where such services are required for safety reasons. Commenters stated their belief that applying the therapy assistant modifiers to discount payment for these services is not justified.

Many commenters stated they objected to the use of the term ''concurrent'' when applying the 10 percent standard for purposes of outpatient therapy services because it conflicts with the definition of ''concurrent'' as it applies to the SNF Part A patient. The SNF Minimum Data Set Resident Assessment Instrument (MDS–RAI) manual guidance defines ''concurrent'' to include the number of minutes of therapy when the therapist or assistant is treating two residents at the same time. Some commenters also disagreed with our use of the term ''concurrent'' because that term is not currently defined for outpatient therapy services in statute, regulation, or in our manuals to ''reflect when two clinicians (therapist and therapist assistant) are providing care to a beneficiary at the same time.'' These commenters recommended that CMS adopt the term ''team'' instead, based on a reference to a document on the CMS therapy services website titled ''11 Part B Billing Scenarios,'' because they stated it describes care being delivered to one patient at the same time by two professionals as ''team-based therapy.''

Other commenters suggested that instead of ''concurrent,'' that we use the term ''in tandem'' to describe the cases where a therapist and a therapy/therapist assistant are jointly furnishing services to a patient at the same time. One commenter recommended that CMS reconsider its definition of ''concurrent'' therapy and align it with the definition in Part A.

Some commenters supported our proposal including a few commenters that agreed there should be a payment differential for the services furnished by a therapy assistant; and, several stated they fully supported of all of the proposals. A few commenters shared their concerns that they have observed therapy assistants practicing outside their scope of practice and their level of training—such as managing a patient's plans of care, some without any therapist supervision.

Many commenters urged CMS to restructure the proposal to recognize as services furnished in whole or in part by therapy assistants only those minutes that the therapy assistant spends independently with the patient when the therapist is absent.

Response: After a review of commenters' concerns and our current policies, we are persuaded to reconsider our interpretation of what time counts as services furnished in whole or in part by therapy assistants, including for purposes of applying the 10 percent standard. We agree with commenters that we should not count the time when a therapist and a therapist assistant furnish services to the same patient at the same time. We believe this

interpretation is appropriate because we agree with commenters that when a therapist and therapist assistant furnish services together, the therapist is fully furnishing the service. Also, any time that the therapy assistant furnishes services alone or independent of the therapist is time that the therapist can be credited for furnishing services to a different patient. We also note the commenters' incorrect use of the term ''clinicians'' to refer to the both the therapist and the therapy assistant. We clarify that the term clinician refers only the physical or occupational therapist and that a therapy assistant is considered a qualified professional when furnishing services under the supervision of a therapist. For purposes of Medicare, therapy assistants are limited in the services they may furnish and may not supervise other therapy caregivers (see MBPM, Chapter 15, section 230.1 and 230.2).

We agree with commenters that using the term ''concurrent'' could be confusing because it is used for the SNF Part A patient to represent the number of minutes that a therapist or therapy assistant is treating two patients at the same time. Given that we are not finalizing the proposal to count the minutes of service furnished by the assistant together with the therapist, we no longer have a need to use the ''concurrent'' term. Regarding the suggestion that we use the term ''team'' instead of concurrent, we also do not define in our manuals the term ''team'' because we believe it is ambiguous. We have only used the term ''team'' in the ''Team'' billing scenario in one of the ''11 Billing Scenarios'' where it is used in an example in which the physical therapist and occupational therapist furnish all the minutes of a 30-minute service together—only the physical therapist or occupational therapist can bill for each 15 minute unit, but not both.

We find the commenters' concerns persuasive and are revising our proposed policy so that the time spent by a PTA/OTA furnishing a therapeutic service ''concurrently,'' or at the same time, with the therapist will not count for purposes of assessing whether the 10 percent standard has been met. Instead, we are finalizing a policy that only the minutes that the PTA/OTA spends independent of the therapist will count towards the 10 percent *de minimis* standard. We are revising our regulation text at §§ 410.59 (outpatient occupational therapy), 410.60 (physical therapy), and 410.105 (for PT and OT CORF services) accordingly. In the CY 2020 PFS proposed rule, we provided detailed examples of clinical scenarios to illustrate how the 10 percent *de minimis* standard would be applied under our proposals when therapists and their assistants work together concurrently or separately to treat the same patient on the same day (84 FR 40562 through 40564). We intend to provide further detail regarding examples of clinical scenarios to illustrate our final policies regarding the applicability of the therapy assistant modifiers through information that we will post on the *cms.gov* website.

Comment: Commenters opposed our proposal to apply the 10 percent time standard, for billing purposes, to all the billed units of a service defined by a single procedure code, and urged CMS to not finalize the proposal. These commenters requested that instead CMS finalize a policy that assesses the 10 percent standard for each 15-minute unit of each procedure code. Commenters noted that the proposal was contrary to the response to comments in the CY 2019 PFS final rule (83 FR 59659) in which we provided an example of how our systems would allow them to bill for 15-minute units of a timed service on 2 separate claim lines—one with an assistant modifier and the other without. Some commenters stated that the proposal would not allow proper payment when a therapist fully furnishes 30 minutes of a timed service, then hands off to a therapy assistant who fully performs another 15 minutes of the same service. Many commenters stated that the proposed policy does not reflect congressional intent because it would discount the therapists' services, rather than therapy assistants' services.

Response: We acknowledge that we provided a hypothetical billing example in the CY 2019 PFS final rule suggesting that our policy would allow the number of 15-minute units of a code furnished by the PT/OT and the PTA/OTA to be listed separately on two different claim lines, and that the example differed from the proposal we developed for the CY 2020 PFS proposed rule. As the commenters noted, we proposed, for billing purposes, that each outpatient therapy service that is subject to the 10 percent *de minimis* standard would be identified on the claim by a single procedure code, for both untimed codes and codes described in 15-minute-unit increments. After consideration of the public comments on our proposal and further reflection on our manual requirements to document timed codes, we find the commenters' concerns persuasive and, for purposes of billing, we are finalizing a revised definition of a service to which the *de minimis* standard is applied to include untimed codes and each 15-minute unit of codes described in 15-minute increments as a service. Accordingly, we are revising our final policy in response to comments to allow the separate reporting, on two different claim lines, of the number of 15-minute units of a code to which the therapy assistant modifiers do not apply, and the number of 15-minute units of a code to which the therapy assistant modifiers do apply. In the CY 2020 PFS proposed rule, we provided detailed examples of clinical scenarios to illustrate how the 10 percent *de minimis* standard would be applied under our proposals (84 FR 40562 through 40564). The revised policy we are finalizing here will apply generally in the same way as illustrated in those examples, except for the difference in the minutes of time that are counted toward the 10 percent standard (not counting the minutes furnished together by a therapist and therapy assistant), the application of the 10 percent standard to each billed unit of a timed code rather than to all billed units of a timed code, and the billing on two separate claim lines of the units of a timed code to which the therapy assistant modifiers do and do not apply. We intend to provide further detail regarding examples of clinical scenarios to illustrate our final policies regarding the applicability of the therapy assistant modifiers through information that we will post on the *cms.gov* website.

Comment: Nearly all commenters opposed our proposal to require that the treatment notes explain, in a short phrase or statement, the application or non-application of the therapy assistant modifier for each therapy service furnished. Many of these commenters stated that the statute does not require documentation to explain why a modifier was or was not applied for each code. Most commenters stated that the proposed documentation requirements associated with the *de minimis* standard for the therapy assistant modifiers are exceedingly burdensome and conflict with the Administration's ''Patients over Paperwork Initiative.'' The commenters stated that it is unreasonable to impose a new documentation requirement on therapists and therapy providers that is duplicative of current requirements. Many commenters stated that the Medicare Benefit Policy Manual (MBPM) already includes extensive documentation requirements, and that the Medicare Claims Processing Manual (MCPM) includes extensive detail on how to count minutes for therapy services.

Many commenters stated that if a therapist or therapy provider has a

mechanism to provide evidence as to whether a specific service was furnished independently by a therapist or an assistant, or was furnished ''in part'' by an assistant, in sufficient detail to permit a medical record reviewer to determine whether the *de minimis* threshold was met, they should not also be required to separately document this information in a narrative note. A few of the commenters opposing the addition of narrative phrases for each service stated that we should revise our current subregulatory guidance to include a statement such as the following: ''The provider should have a mechanism in place to provide evidence whether a specific service was furnished independently by a therapist or an assistant, or was furnished ''in part'' by an assistant in sufficient detail to permit the determination of whether the ''*de minimis*'' threshold was met.'' Another commenter stated that it is expected and appropriate for the documentation in the medical record to specify whether a certain service was furnished independently by a therapist or an assistant or was furnished ''in part'' by an assistant in enough detail to permit a medical record reviewer to determine whether the *de minimis* threshold was met.

Many commenters stated that they believe our proposed documentation requirement to explain in the medical record the use or non-use of the modifiers would serve as another tool for medical reviewers to use against therapy providers to justify a technical denial even though the medical record may otherwise contain sufficient documentation to justify the use or non-use of the CQ/CO modifier.

Many commenters submitted comments that were specific to our request for comment on documentation of the minutes for services furnished by the PTA/OTA as a means to avoid possible additional burden associated with a contractor's medical review process conducted for these services. Nearly all of the commenters stated they opposed adding a requirement to include a narrative phrase in the treatment note and requiring documentation of the minutes as duplicative of existing documentation requirements. One commenter, also not in favor of requiring the addition of narrative phrases to the medical record because they do not believe such phrases provide value to patient care or providers, stated that the therapy provider should document the number of minutes provided solely by the assistant and that this should be adequate to support the use and nonuse of the CO/CQ modifiers—citing an example that included ''CPT 97110—Assistant provided 8 minutes, Therapist provided 24 minutes'' and ''CPT 97530—Assistant provided 22 minutes, Therapist provided 0 minutes.''

Several commenters supported the proposed documentation requirements. One commenter stated they have already begun taking steps to support billing compliance via their electronic health record that creates a selection to attach the appropriate PTA/OTA modifier and includes the creation of a ''smart phrase'' which the therapist can document to support compliance of billing and review.

Response: We appreciate the comments regarding our documentation proposal. After consideration of the comments and a review of our manual provisions, we find many of the commenters' suggestions persuasive. We agree that the addition of narrative phrases for each service may be duplicative of existing documentation requirements in the MBPM, chapter 15, section 220 and in Chapter 5, MCPM. Although a few commenters supported the addition of narratives, we also took note of the many commenters who told us that therapists and therapy providers should not be required to include a narrative for each service explaining the application or non-application of the therapy assistant modifiers when the medical record contains evidence as to whether a specific service was furnished independently by a therapist or an assistant, or was furnished ''in part'' by an assistant, in sufficient detail to permit a medical record reviewer to determine whether the de minimis threshold was met.

As a result, we are not finalizing the proposed documentation requirement to explain in the treatment note, in a short phrase or statement, the application or non-application of the therapy assistant modifier for each therapy service furnished; nor are we finalizing a requirement that the therapist and therapy assistant minutes be included in the documentation. Instead, we remind therapists and therapy providers that correct billing requires sufficient documentation in the medical record to support the codes and units reported on the claim, including those reported with and without an assistant modifier.

Further, we clarify that we would expect the documentation in the medical record to be sufficient to know whether a specific service was furnished independently by a therapist or a therapist assistant, or was furnished ''in part'' by a therapist assistant, in sufficient detail to permit the determination of whether the 10 percent standard was exceeded.

Comment: Many commenters expressed concern that the application of the therapy assistant modifiers is likely to result in drastic underpayments for outpatient therapy services beginning in 2022, which they believe would severely restrict beneficiary access to vital therapy services, particularly in rural and underserved areas. Other commenters specifically requested that CMS exempt rural areas from the therapy assistant modifier policy.

Response: While we appreciate the concerns raised about the potential effects of the therapy assistant modifier policy, we do not believe that section 1834(v) of the Act permits us to exempt the application of the PTA/OTA modifier policies in rural and underserved areas. We intend to monitor the implementation of the therapy assistant modifiers, including any changes to access to outpatient therapy services.

Comment: One commenter stated their concerns about the correct ordering of modifiers on claims for therapy services to assure correct payment, but without adding to therapists' or therapy providers' administrative burden. They based their concerns on a CMS longstanding FAQ, which states that modifiers that impact payment should be in the first position, and are seeking clarification as to whether the CQ or CO modifier would need to be in the first position on claims for PT services (modifier GP) and OT services (modifier GO) where one of those new modifiers applies. The commenters stated that if the CQ or CO modifier is required to be in the first position, that would need to be done manually because therapists and therapy providers are not able to program their chargemasters to accommodate every possible modifier combination to meet Medicare and non-Medicare reporting requirements.

Response: We appreciate the commenter's comments. We note that we do not have central standard systems edits in place to reject or return claims for PT or OT services if the CQ or CO modifier is not in the first modifier position. However, some CMS contractors processing professional claims may have systems logic in place that would do so. We recently issued instructions to our contractors to reorder modifiers for PT and OT services so that claims with the therapy assistant modifiers are not returned. This reordering will be effective for claims containing CQ and CO modifiers with dates of service on and after January 1, 2020.

3. Therapy KX Modifier Threshold Amounts

The KX modifier thresholds, as discussed above in this section, were established through section 50202 of the Bipartisan Budget Act (BBA) of 2018. Formerly referred to as therapy caps, these KX modifier thresholds are a permanent provision of the law, meaning that the statute does not specify an end date. These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the MEI. Specifically, these amounts are calculated by updating the previous year's amount by the MEI for the upcoming calendar year and rounding to the nearest $10.00. Increasing the CY 2019 KX modifier threshold amount of $2,040 by the CY 2020 MEI of 1.9 percent and rounding to the nearest $10.00 results in a CY 2020 KX threshold amount of $2,080 for PT and SLP services combined and $2,080 for OT services.

Section 50202 of the Bipartisan Budget Act of 2018 also added section 1833(g)(7)(B) of the Act which retains the targeted medical review process, but at a lower threshold amount of $3,000 (until CY 2028) as detailed above in this section. Accordingly, for CY 2020, the MR threshold is $3,000 for PT and SLP services combined and $3,000 for OT services. Some, but not all claims exceeding the MR threshold amount are subject to review, under the established targeted review process. For information on the targeted manual medical review process, go to *https://www.cms.gov/ResearchStatistics-Data-and-Systems/MonitoringPrograms/Medicare-FFS-CompliancePrograms/Medical-Review/TherapyCap.html.*

We track each beneficiary's incurred expenses for therapy services annually and counts them toward the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount for services of CMS-designated ''always therapy'' services. As explained previously in this section, we apply the PFS-rate accrual process to outpatient therapy services furnished by critical access hospitals (CAHs) even though they may be paid on a cost basis (effective January 1, 2014).

When the expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. By using the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services that exceed the KX modifier thresholds but do not include the KX modifier are denied.

N. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010 and CY 2015. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.E. of this final rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the federal government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of

services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that included the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist we also include a summary of stakeholder reactions to our approach. We note that many commenters and stakeholders have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under

the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We received several comments regarding our methodologies for work valuation in response to the CY 2020 PFS proposed rule and those comments are summarized below.

Comment: Several commenters disagreed with our reference to older work time sources, and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource-based. Commenters also stated that it was invalid to draw comparisons between the current work time and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important element in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times. It also would undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS. Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters urged CMS to determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since

the statute explicitly identifies time as one of the two elements of the work RVUs.

We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this current CY 2020 PFS final rule, CPT codes 52442 (*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant*) and 92627 (*Evaluation of auditory function for surgically implanted device(s) candidacy or post-operative status of a surgically implanted device(s); each additional 15 minutes*) share the identical work time of 15 minutes but have very different work RVUs of 1.01 and 0.33 respectively. In addition, CPT codes 11983 (*Removal with reinsertion, non-biodegradable drug delivery implant), 64446 (Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)*), and 78804 (*Rp L.T.I.D. w/ flow when performed, wholebody 2 or more days*) all share the same intraservice work time of 15 minutes and total work time of 40 minutes but each code has a different work RVU. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple different factors employed in our review process. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

We also want to clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). With regards to the invocation of clinically relevant relationships by the commenters, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters discouraged the use of valuation based on work RVU increments. Commenters stated that this methodology inaccurately treats all components of the physician time as having identical intensity and would lead to incorrect work valuations. Commenters stated that CMS should carefully consider the clinical information justifying the changes in physician work intensity provided by the RUC and other stakeholders.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate stakeholder feedback, we will seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. We also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 26 contains a list of codes and descriptors for which we are finalizing work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2019. The work RVUs, work time and other payment information for all CY 2020 payable codes are available on the CMS website under downloads for the CY 2020 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs to Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially

misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 27 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that would be common across codes. Refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also note that approximately half of the refinements listed in Table 27 result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

We also note that the direct PE inputs for CY 2020 are displayed in the CY 2020 direct PE input files, available on the CMS website under the downloads for the CY 2020 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* The inputs displayed there have been used in developing the CY 2020 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the

RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2020, we received invoices for several new supply and equipment items. Tables 28 and 29 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this final rule, Determination of Practice Expense Relative Value Units, we encouraged stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encouraged stakeholders to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 28 and 29 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the public use files for the PFS proposed and final rules for each year display the services subject to the MPPR for diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services. We also include a list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2020 are available on the CMS website under downloads for the CY 2020 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263). For more information regarding the history of the OPPS cap, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

4. Proposed Valuation of Specific Codes for CY 2020

(1) Tissue Grafting Procedures (CPT Codes 15769, 15771, 15772, 15773, and 15774)

CPT code 20926 (*Tissue grafts, other (e.g., paratenon, fat, dermis)*), was identified through a review of services with anomalous sites of service when compared to Medicare utilization data. The CPT Editorial Panel subsequently replaced CPT code 20926 with five codes in the Integumentary section to better describe tissue grafting procedures.

We proposed the RUC-recommended work RVUs of 6.68 for CPT code 15769 (*Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)*), 6.73 for CPT code 15771 (*grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50cc or less injectate*), 2.50 for CPT code 15772 (*grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50cc injectate, or part thereof (list separately in addition to code for primary procedure)*), 6.83 for CPT code 15773 (*grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25cc or less injectate*), and 2.41 for CPT code 15774 (*grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25cc injectate, or part thereof (list separately in addition to code for primary procedure)*).

We proposed the RUC-recommended direct PE inputs for this code family without refinement.

We received public comments on the proposed valuation of the codes in the Tissue Grafting Procedures family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported our proposal to use the RUC-recommended work RVUs for these codes.

Response: We appreciate the support for our proposal from the commenter. After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Tissue Grafting Procedures family as proposed.

(2) Drug Delivery Implant Procedures (CPT Codes 11981, 11982, 11983, 20700, 20702, 20704, 20701, 20703, and 20705)

CPT codes 11980–11983 were identified as potentially misvalued since the majority specialty found in recent claims data differs from the two specialties that originally surveyed the codes. The current valuation of CPT code 11980 (*Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)*) was reaffirmed by the RUC as the physician work had not changed since the last review. The CPT Editorial Panel revised the other three existing codes in the family and created six additional add-on codes to describe orthopaedic drug delivery. These codes were surveyed and reviewed for the October 2018 RUC meeting.

CPT code 11980 (*Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)*) with the current work value of 1.10 RVUs and 12 minutes of intraservice time, and 27 minutes of total time, was determined to be unchanged since last reviewed and was recommended by the RUC to be maintained. We concur. We did not propose any direct PE refinements to CPT code 11980. CPT code 11981 (*Insertion, non-biodegradable drug delivery implant*) has a current work RVU of 1.48, with 39 minutes of total physician time. The specialty society survey recommended a work RVU of 1.30, with 31 minutes of total physician time and 5 minutes of intraservice time. The RUC recommended a work RVU of 1.30 (25th percentile), with 30 minutes of total physician time and 5 minutes of intraservice time. For comparable reference CPT codes to CPT code 11981, the RUC and the survey respondents had selected CPT code 55876 (*Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple (work RVU = 1.73, 20 minutes intraservice time and 59 total minutes)*) and CPT code 57500 (*Biopsy of cervix, single or multiple, or local excision of lesion, with or without fulguration (separate procedure) (work RVU = 1.20, 15 minutes intraservice time and 29 total minutes)*). The RUC further offered for comparison, CPT code 67515 (*Injection of medication or other substance into Tenon's capsule (work RVU = 1.40 (from CY 2018), 5 minutes intraservice time and 21 minutes total time*)), CPT code 12013 (*Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm (work RVU = 1.22 and 27 total minutes)*) and CPT code 12004 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm) (work RVU = 1.44 and 29 total minutes)*). In addition, we offered CPT code 67500 (*Injection of medication into cavity behind eye) (work RVU = 1.18 and 5 minutes intraservice time and 33 total minutes*) for reference. Given that the CPT code 11981 incurs a 23 percent reduction in the new total physician time and with reference to CPT code 67500, we proposed a work RVU of 1.14, and accepted the survey-recommended 5 minutes for intraservice time and 30 minutes of total time. We did not propose any direct PE refinements to CPT code 11981.

CPT code 11982 (*Removal, non-biodegradable drug delivery implant*) has a current work RVU of 1.78, with 44 minutes of total physician time. The specialty society survey recommended a work RVU of 1.70 RVU, with 10 minutes of intraservice time and 34 minutes of total physician time. The RUC also recommended a work RVU of 1.70, with 10 minutes of intraservice time and 33 minutes of total physician time. The RUC confirmed that removal (CPT code 11982), requires more intraservice time to perform than the insertion (CPT code 11981). For comparable reference codes to CPT code 11982, the RUC and the survey respondents had selected CPT code 54150 (*Circumcision, using clamp or other device with regional dorsal penile or ring block) (work RVU = 1.90, 15 minutes intraservice time and 45 total minutes)*) and CPT code 12004 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm) (work RVU = 1.44, with 17 minutes intraservice time and 29 minutes total time)*). We offered CPT code 64486 (*Injections of local anesthetic for pain control and abdominal wall analgesia on one side) (work RVU = 1.27, 10 minutes intraservice time and 35 total minutes)*) for reference. Given that the CPT code 11982 incurs a 25 percent reduction in the new total physician time and with reference to CPT code 64486, we proposed a work RVU of 1.34, and accepted the RUC-recommended 10 minutes for intraservice time and 33 minutes of total time. We did not propose any direct PE refinements to CPT code 11982.

CPT code 11983 (*Removal with reinsertion, non-biodegradable drug delivery implant*) has a current work RVU of 3.30, with 69 minutes of total physician time. The specialty society survey recommended a work RVU of 2.50 RVU, with 15 minutes of intraservice time and 41 minutes of total physician time. The RUC also recommended a work RVU of 2.10, with 15 minutes of intraservice time and 40 minutes of total physician time. The RUC confirmed that CPT code 11983 requires more intraservice time to perform than the insertion CPT code 11981. For comparable reference codes to CPT code 11983, the RUC and the survey respondents had selected CPT code 55700 (*Biopsy, prostate; needle or punch, single or multiple, any approach) (work RVU = 2.50, 15 minutes intraservice time and 35 total minutes)*), CPT code 54150 (*Circumcision, using clamp or other device with regional dorsal penile or ring block) (work RVU = 1.90, 15 minutes intraservice time and 45 total minutes)*) and CPT code 52281 (*Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female) (work RVU = 2.75 and 20 minutes intraservice time and 46 minutes total time)*). We offered CPT code 62324 (*Insertion of indwelling catheter and administration of substance into spinal canal of upper or middle back) (work RVU = 1.89, 15 minutes intraservice time and 43 total minutes)*) for reference. Given that the CPT code 11983 incurs a 42 percent reduction in new total physician time and with reference to CPT code 62324, we proposed a work RVU of 1.91, and accepted the RUC-recommended 15 minutes for intraservice time and 40 minutes of total time. We did not propose any direct PE refinements to CPT code 11983.

The new proposed add-on CPT codes 20700–20705 are intended to be typically reported with CPT codes 11981–11983, with debridement or arthrotomy procedures done primarily by orthopedic surgeons. The specialty society's survey for CPT code 20700 (*Manual preparation and insertion of drug delivery device(s), deep (e.g., subfascial)*) found a 2.00 work RVU value at the median and a 1.50 work

RVU value at the 25th percentile, with 20 minutes of intraservice time and 30 minutes of total physician time, for the preparation of the antibiotic powder and cement, rolled into beads and threaded onto suture for insertion into the infected bone. The RUC recommended a work RVU of 1.50, with 20 minutes of intraservice time and 27 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof) (work RVU = 1.80, and 30 minutes intraservice time)*), CPT codes 64484 (*Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level) (work RVU = 1.00 and 10 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation) (work RVU = 2.09 and 20 minutes intraservice time)*). Our review of similar add-on CPT codes yielded CPT code 64634 (*Destruction of upper or middle spinal facet joint nerves with imaging guidance) (work RVU = 1.32 and 20 minutes intraservice time)*). We proposed for CPT code 20700, a work RVU of 1.32, and accept the RUC-recommended 20 minutes of intraservice time and 27 minutes of total time.

The specialty society's survey for CPT code 20702 (*Manual preparation and insertion of drug delivery device(s), intramedullary*) found a 3.25 work RVU value at the median and a 2.50 work RVU value at the 25th percentile, with 25 minutes of intraservice time and 32 minutes of total physician time, for the preparation of the ''antibiotic nail'' ready for insertion into the intramedullary canal with fluoroscopic guidance. The RUC recommended a work RVU of 2.50, with 25 minutes of intraservice time and 32 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof) (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (work RVU = 4.88 and 45 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 15 minutes intraservice time)*). We find that the reference CPT code 11047, with 30 minutes of intraservice time, is suitable, but we adjust our proposed work RVU of 1.70 to account for the 25 minutes, instead of our reference code's 30 minutes of intraservice time (and the 32 minutes of total time), for CPT code 20702.

The specialty society's survey for CPT code 20704 (*Manual preparation and insertion of drug delivery device(s), intra-articular*) found a 4.00 work RVU value at the median and a 2.60 work RVU value at the 25th percentile, with 30 minutes of intraservice time and 37 minutes of total physician time, for the preparation of the antibiotic cement inserted into a pre-fabricated silicone mold, when after setting up, will be cemented to the end of the bone (with the joint). The RUC recommended a work RVU of 2.60, with 30 minutes of intraservice time and 37 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (work RVU = 4.88 and 45 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 20 minutes intraservice time)*). We find that the reference CPT code 11047, with 30 minutes of intraservice time, is a suitable guide and we proposed the work RVU of 1.80 with the RUC-recommended 30 minutes of intraservice time and 37 minutes of total time, for CPT code 20704.

The specialty society's survey for CPT code 20701 (*Removal of drug delivery device(s), deep (e.g., subfascial)*) found a 1.75 work RVU value at the median and a 1.13 work RVU value at the 25th percentile, with 15 minutes of intraservice time and 18 minutes of total physician time. The work includes a marginal dissection to expose the drug delivery device and to remove it. The RUC recommended a work RVU of 1.13, with 18 minutes of total physician time and 15 minutes of intraservice time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 64484 (*Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (work RVU = 1.00 and 10 minutes intraservice time)*), and CPT code 64480 (*Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional level (work RVU = 1.20 and 15 minutes intraservice time)*). We proposed the RUC-recommended work RVU of 1.13 with 15 minutes of intraservice time and 18 minutes of total time for 20701.

The specialty society's survey for CPT code 20703 (*Removal of drug delivery device(s), intramedullary*) found a 2.50 work RVU value at the median and a 1.80 work RVU value at the 25th percentile, with 20 minutes of intraservice time and 23 minutes of total physician time. The work includes a marginal dissection, in addition to what was in the base procedure, to loosen and expose the drug delivery device and to remove it, any remaining drug delivery device shards that may have broken off. The RUC recommended a work RVU of 1.80, with 20 minutes of intraservice time and 23 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT codes 37253 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (work RVU = 1.44 and 20 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 15 minutes intraservice time)*). We proposed the RUC-recommended work RVU of 1.80 with 20 minutes of intraservice time and 23 minutes of total time for 20703.

The specialty society's survey for CPT code 20705 (*Removal of drug delivery*

device(s), intra-articular) found a 3.30 work RVU value at the median and a 2.15 work RVU value at the 25th percentile, with 25 minutes of intraservice time and 28 minutes of total physician time. The work includes the removal of the intra-articular drug delivery device that is cemented to both sides of the joint without removing too much bone in the process. The RUC recommended a work RVU of 2.15, with 25 minutes of intraservice time and 28 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 36476 (*Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (work RVU = 2.65 and 30 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 15 minutes intraservice time)*). We proposed the RUC-recommended work RVU of 2.15 with 25 minutes of intraservice time and 28 minutes of total time for 20705.

We received public comments on the proposed valuation of the codes in the Drug Delivery Implant Procedures family. The following is a summary of the comments we received and our responses.

Comment: In an overall comment to code valuations, but also pertinent to this section, one commenter stated that they are increasingly concerned that CMS is eschewing the bedrock principles of valuation within the RBRVS (namely, magnitude estimation, survey data and clinical expertise) in favor of arbitrary mathematical formulas and in their opinion, make a distinction in the different types of physician time, which are ''CMS/Other'' time source, ''Harvard'' time source, and ''RUC'' time source (from physician surveys).

Response: As we have discussed in previous rules, we agree that it is important to use the most recent data available regarding time, and we note that when many years have passed between when physician times are measured, significant discrepancies can occur. However, we also continue to believe that our operating assumption regarding the validity of the existing time values as a point of comparison is critical to the integrity of the current relative value system.

The physician times and intensities currently associated with codes, play important roles in PFS ratesetting in their comparativeness to each other, in establishing work RVUs. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS. Given that the process under which codes are often valued by comparison to codes with similar times, we acknowledge the distinction between ''CMS/Other'' times, ''Harvard'' times, and ''RUC'' physician surveyed times, but we cannot apply different validation weights to any of these labels. They are all physician times data collected over many years. We understand that some time values may not have been reviewed or re-surveyed in a number of years, but that alone is not an indicator of how accurate or inaccurate a time value may be. We believe that over the years as more codes are being reviewed and examined, that collectively the entire fee schedule of procedure codes should all naturally align themselves into a very reliable and more accurate system reflecting every code's relativity to one another (in their work RVUs, in their procedure times, and in their work intensities).

We believe that it is crucial that the code valuation process with existing work times and work RVUs in the PFS ratesetting processes are accurate. We recognize that adjusting work RVUs for changes in physician times is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we always try to apply various methodologies to identify several potential work values for individual codes. CMS CPT code review not only examines the relationships between work, time, and intensity, but we also look at magnitude and rank order anomalies particularly in families or groups of codes that are closely related, but may differ slightly in degrees found in their clinical descriptions and possibly in the typical beneficiary populations that each code might serve. Among these codes, we try to keep the differences in times, work, and intensity properly distant between each other. In some cases, where there are marked improvements in medical techniques and technological assistance, we may see better efficiencies in physician's work, and thus decreases in physician's times, but we also recognize that some improvements may introduce greater complexity and either a greater intensity and/or increase in physician times.

We reiterate that we believe it would be irresponsible to ignore or discount ''CMS/Other'' times or ''Harvard'' times in our data system and that we need to consider all times and all intensities and all procedure code's clinically relevant relatedness (or non-relatedness) to each other, in establishing more refined work RVUs for PFS services. Also note that ''RUC'' physician times are not always necessarily AMA RUC surveyed times. CMS may have adjusted AMA RUC surveyed times in our annual review of all HCPCS codes, as well as times that the AMA labels as ''Harvard'' or ''CMS/Other'' physician times.

Comment: One commenter stated the current source of time for CPT code 11981 is CMS/Other. The commenter also stated the crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. The commenter noted this code's source of time is CMS/Other, implying that the time was merely crosswalked or selected by a single CMS staffer some time ago, and CMS should not compare the valid survey time to the initial CMS/Other time because the initial CMS/Other source data is flawed and has no validity for comparison.

Response: The current physician time for CPT code 11981 is 39 minutes of total time and the current work RVUs is 1.48. The AMA RUC's new recommended times are 5 minutes intra-service time and 30 minutes total time (surveyed total time was 31 minutes). We accept the AMA RUC newly surveyed-recommended times. The AMA RUC selected multiple reference CPT codes 55876, 57500, 67515, 12013, and 12004 that they believe to be comparable to CPT code 11981. We selected the reference CPT code 67500, with 5 minutes intra-time and 33 minutes total time, which we believe to be a better reference code and is clearly comparable to the accepted recommended times for CPT code 11981. CPT code 67500 was last reviewed in 2005 and the time source was from the ''RUC'' who no doubt surveyed this code at that time, so CPT code 67500's time source is not ''CMS/Other'', which we do not believe is material to selecting a reference code for physician work and time. As discussed above, we believe there is no comparison flaw in time or work RVUs, based on the AMA RUC's distinction labeling of ''RUC'' times, ''CMS/Other

times'', or ''Harvard'' times. We believe that it is crucial that the code valuation process take place with the understanding that all existing work times, used in the PFS ratesetting processes, are accurate. Our reference CPT code 67500's work RVU is 1.18.

Comment: Some commenters stated that CPT code 11981 is not clinically related to our reference code of CPT code 67500, as it relates to both the physician description of work and the typical patient population treated with this service.

Response: As part of our review, we look for comparable codes that are similar in physician service times, work RVUs, work intensity, and clinical similarity. As discussed above, we believe there is no comparison flaw in time or work RVUs, based on the AMA RUC's distinction labeling of ''RUC'' times, ''CMS/Other times'', or ''Harvard'' times. We believe that it is crucial that the code valuation process take place with the understanding that all existing work times, used in the PFS ratesetting processes, are accurate. We continue to believe that CPT code 67500 is the better reference code for us to use to establish an appropriate valuation for CPT code 11981. Both codes require 5 minutes intra-service time and CPT code 11981 takes 30 minutes total time while CPT code 67500 takes a similar amount of 33 minutes of total time.

While the commenters object to CMS' reference CPT code of 67500 as being clinically related to CPT code 11981, the commenter's additional selected CPT reference codes of 67515, 12013, and 12004, are also very different from CPT code 11981. There appears to be a discrepancy in the AMA RUC's CPT (referencing) code 67515 (*Injection of medication or other substance into Tenon's capsule, work RVU = 1.40, 5 minutes intra-service time and 21 minutes total time).* CMS' data indicates a different work RVU and physician times for this code. For CPT code 67515, we have on record for work RVU = 0.75, 3 minutes intra-service time and 13 minutes total time.

The AMA RUC CPT (referencing) codes 12013 and 12004 appears to be at least partially valued on the length of a wound repair (2.6 cm to 5.0 cm or 7.6 cm to 12.5 cm), and assuming that the longer the wound repair is, the more work and physician time is required to perform the procedure. CPT code 11981 does not have this ''size length'' characteristic, so we question if CPT codes 12013 or 12004 more or less are a valid comparison referencing codes to CPT code 11981 where there is not this ''size length'' characteristic. As we have stated, the clinical relatedness of codes are not always exact, nor always available.

Comment: The RUC survey respondents offered CPT code 55876 (*Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple (work RVU = 1.73, 20 minutes intra-service time and 59 total minutes)*) and 57500 (*Biopsy of cervix, single or multiple, or local excision of lesion, with or without fulguration (separate procedure) (work RVU = 1.20, 15 minutes intra-service time and 29 total minutes)*) as referencing codes to CPT code 11981.

The AMA RUC recommendation offered CPT code 67515 (*Injection of medication or other substance into Tenon's capsule (work RVU = 1.40, 5 minutes intra-service time and 21 minutes total time)*), MPC codes 12013 (*Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm (work RVU = 1.22, 15 minutes intra-service time and 27 total minutes)*) and 12004 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm (work RVU = 1.44 15 minutes intra-service time and 29 total minutes)*). The AMA RUC offer these reference codes to have similar physician work and total time to CPT code 11981.

Response: All of the commenter's reference comparison CPT codes have far more intra-service time than CPT code 11981 intra-service time of 5 minutes, except for CPT code 67515, but this code appears to only have 3 minutes of intra-service time and 0.75 work RVUs. CMS' CPT (reference) code of 67500 appears to have the closest physician times to CPT code 11981 and their work RVUs should be similar.

After consideration of the public comments for CPT code 11981, we are finalizing the proposed work RVU as 1.14.

Comment: Several commenters stated the current source of time for CPT code 11982 is CMS/Other. Commenters also stated the crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. Commenters noted this code's source of time is CMS/Other, implying that the time was merely crosswalked or selected by a single CMS staffer some time ago. CMS should not compare the valid survey time to the initial CMS/Other time because the initial CMS/Other source data is flawed and has no validity for comparison.

Response: The current physician times for CPT code 11982 are 44 minutes of total time and the current work RVUs is 1.78. The AMA RUC's new recommended times are 10 minutes intra-service time and 33 minutes total time (surveyed total time was 34 minutes). CMS accepts the AMA RUC newly surveyed recommended times and used CPT reference code 64486, with 10 minutes intra-service time and 35 minutes total time, which are clearly comparable to the accepted recommended times for CPT code 11982. CPT code 64486 was introduced by CPT in 2014 and the time source was from the ''RUC'' who no doubt surveyed this code at that time, so CPT code 64486's time source is not ''CMS/Other'', which we do not believe is material to selecting a reference code for physician work and time. As part of our review, we look for comparable codes that are similar in physician service times, work RVUs, work intensity, and clinical relatedness. As discussed above, we believe there is no comparison flaw in time or work RVUs, based on the AMA RUC's distinction labeling of ''RUC'' times, ''CMS/Other times'', or ''Harvard'' times. We believe that it is crucial that the code valuation process take place with the understanding that all existing work times, used in the PFS ratesetting processes, are accurate and there is no comparison flaw. Our reference CPT code 64486's work RVU is 1.27.

Comment: Commenters stated that CPT code 11982 is essentially not clinically related to our reference code of CPT code 64486, in physician description of work and the typical patient population that they treat.

Response: As part of our review, we look for comparable codes that are similar in physician service times, work RVUs, work intensity, and are clinically related. As discussed above, we believe there is no comparison flaw in time or work RVUs, based on the AMA RUC's distinction labeling of ''RUC'' times, ''CMS/Other times'', or ''Harvard'' times. We believe that it is crucial that the code valuation process take place with the understanding that all existing work times, used in the PFS ratesetting processes, are accurate. CPT codes 11982 and 64486 are not clinically related, but their work times and work RVUs are similar. The commenter's selected reference CPT codes of 54150 and 12004, can also be said to be very similar to CPT code 11982 as well. CPT (referencing) code 54150 appears to apply only to the male patient population, where CPT code 11982

applies to both the male and female population. CPT (referencing) code 12004 appears to be at least partially valued on the length of a wound repair (7.6 cm to 12.5 cm), assuming that the longer the wound repair is, the more work and physician time is required to perform the procedure, but CPT code 11982 does not have this ''size length'' characteristic. As previously stated, clinical relatedness between codes are not always exact, nor always available for exact comparison and we continue to believe that CMS' reference CPT code 64486 is equally as valid as the AMA RUC's reference CPT codes.

Comment: The AMA RUC and the survey respondents offered CPT code 54150 (*Circumcision, using clamp or other device with regional dorsal penile or ring block (work RVU = 1.90, 15 minutes intra-service time and 45 total minutes)*) and CPT code 12004 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm (work RVU = 1.44, with 17 minutes intra-service time and 29 minutes total time)*) as comparable reference codes to CPT code 11982.

Response: Both AMA RUC reference codes have more intra-service times than CPT code 11982, so accordingly, they have more work RVUs. We believe CPT code 11982 with 10 minutes of intra-service time should have a work RVU value that is less than the AMA RUC reference codes and less than their recommended 1.70 RVUs. CPT code 64486 physician times are very similar to CPT code 11982's physician times and their work RVUs should be similar.

After consideration of the public comments for CPT code 11982, we are finalizing its work RVU, as proposed, to 1.34 RVUs.

Comment: One commenter stated the current source of time for CPT code 11983 is CMS/Other and the crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. The commenter further stated this code's source of time is CMS/Other, implying that the time was merely crosswalked or selected by a single CMS staffer some time ago. CMS should not compare the valid survey time to the initial CMS/Other time because the initial CMS/Other source data is flawed and has no validity for comparison.

Response: The current physician times for CPT code 11983 are 49 minutes of total time and the current work RVUs is 3.30. The AMA RUC's new recommended times are 15 minutes intra-service time and 40 minutes total time (surveyed total time was 41 minutes). We accept the AMA RUC newly surveyed recommended times and used CPT code 62324, with 15 minutes intra-service time and 43 minutes total time, which are comparable to the AMA RUC recommended times for CPT code 11983. CPT code 62324 was introduced by CPT in 2017 and the time source was from the ''RUC'' who no doubt surveyed this code at that time, so CPT code 62324's time source is not ''CMS/Other'', which we do not believe is material to selecting a reference code for physician work and time. As part of our review, we look for comparable codes that are similar in physician service times, work RVUs, work intensity, and clinically similarity. As discussed above, we believe there is no comparison flaw in time or work RVUs, based on the AMA RUC's distinction labeling of ''RUC'' times, ''CMS/Other times'', or ''Harvard'' times. We believe that it is crucial that the code valuation process take place with the understanding that all existing work times, used in the PFS ratesetting processes, are accurate. We continue to believe that CPT code 62324 is the better reference code to CPT code 11983. Our reference CPT code 62324's work RVU is 1.89.

Comment: Commenters stated that the intensity of the work required to perform CPT code 11983 is not comparable to CMS' reference to injection of anesthetic code 62324 and yet in their original AMA RUC survey for CPT code 11983, the commenter stated the survey respondents indicated that CPT code 11983 (originally 15 minutes intra-service time, 69 minutes total time, and 3.30 work RVUs) overall requires the same or more intensity and complexity to perform as CPT code 55700 (15 minutes of intra-service time, 35 minutes of total time, and 2.50 work RVUs). The RUC noted that since CPT code 11983 has such a low intra-service time and is a 000-day service comparing the intra-service per unit of time (IWPUT) is not a useful comparison.

Response: The commenters stated that CPT (CMS reference) code 62324 (15 minutes intra-service time, 43 minutes total time and their work RVU is 1.89) is less intensive than CPT code 11983 and thus their work RVUs are not comparable. But, the original selected surveyees' reference CPT code of 55700 (15 minutes intra-service time, 35 minutes total time and work RVU is 2.50) has been stated as the same or less intensive than CPT code 11983. Therefore, we question if that is true. If CPT code 55700 (2.50 work RVUs) is the same or less intensive than CPT code 11983, CPT code 11983's proposed work RVU should be 2.50 or greater. The RUC recommended work RVU for CPT code 11983 is 2.10. This is less than 2.50. The survey median yielded 2.50. Further, the AMA RUC asserts that the work RVU for CPT code 11983 should be higher than 1.89 (62324) and also higher than 2.50 (55700) but recommends a proposed work RVU of 2.10. The AMA RUC noted that since CPT code 11983 has such a low intra-service time and is a 000-day service, comparing the intra-service per unit of time (IWPUT) is not a useful comparison. (The AMA RUC also referenced CPT code 54150 (work RVU is 1.90) and CPT code 52281 (work RVU is 2.75) as potential reference codes.

As part of our review, we look for comparable codes that are similar in physician service times, work RVUs, work intensity, and are clinical related. As discussed above, we believe there is no comparison flaw in time or work RVUs, based on the AMA RUC's distinction labeling of ''RUC'' times, ''CMS/Other times'', or ''Harvard'' times. We believe that it is crucial that the code valuation process take place with the understanding that all existing work times, used in the PFS ratesetting processes, are accurate and there is no comparison flaw. As for the question of our selection of CPT code 62324 being more or less clinically related to CPT code 11983, as we have previously stated in this regard, perfect clinical relatedness is not always available in selecting a reference code. The same is true with the AMA RUC selection of reference code(s).

After consideration of the public comments for CPT code 11983, we are finalizing the work RVU, as proposed, of 1.91 RVUs.

Comment: One commenter stated that CMS may have a typo in the text of the proposed rule because the CY 2020 PFS proposed rule Physician Time file indicated the same time as the RUC recommended with a total of 27 minutes for CPT code 20700.

Response: The commenter is correct that there was a typo in the text concerning CPT code 20700 (206X0) where in one sentence the total physician time was stated as 27 minutes and then in a subsequent sentence it was stated as 20 minutes. The typo has been corrected. Upon further review of the AMA RUC recommendations and CMS own examination, we believe that our proposed RVU value of 1.32 work RVUs on balance is not entirely supportable, and we are instead adopting the AMA RUC recommended

value of 1.50 work RVUs for CPT code 20700.

Comment: Concerning the paragraph on CPT code 20702 (206X1), commenters noted that there were two typos in the proposed rule for the CMS reference CPT code 11047. The commenter stated that the RUC total time recommended for CPT code 20702 (206X1) is 32 minutes not 38 minutes and the total time for CMS reference code 11047 is 31 minutes not 32 minutes, but both are listed correctly in the CY 2020 PFS proposed rule Physician Time file.

Response: The commenter is correct that there was a typo in the text concerning CPT code 20702 (206X1) where in one sentence the total physician time was stated as 38 minutes when it was actually 32 minutes. The 38 minutes was from the survey total time for this code, and it was inadvertently used. The typo has been corrected. Upon further review of the AMA RUC recommendations and CMS' own examination, we believe that our proposed value of 1.70 work RVUs on balance is not entirely supportable, and we are instead adopting the AMA RUC recommended value of 2.50 work RVUs for CPT code 20702.

Comment: One commenter noted that there is a typo in the text of the proposed rule for CPT code 20704 (206X2). The commenter stated the RUC recommended 5 minutes evaluation pre-service time, 30 minutes intra-service time and 2 minutes post-service time, totaling 37 minutes for CPT code 20704 (206X2), not 45 minutes. The physician time for CPT code 20704 (206X2) is listed correctly in the CY 2020 PFS proposed rule Physician Time file.

Response: The commenter is correct that there was a typo in the text concerning CPT code 20704 (206X2) where in one sentence the total physician time was stated as 45 minutes when it was actually 37 minutes. The 45 minutes was this from this CPT code's surveyed total time and the actual AMA RUC recommended total time was 37 minutes. The typo has been corrected. Upon further review of the AMA RUC recommendations and CMS' own examination, we believe our proposed value of 1.80 work RVUs on balance is not entirely supportable and we are instead adopting the AMA RUC recommended value of 2.60 work RVUs for CPT code 20704.

After consideration of the public comments, we are accepting the AMA RUC's surveyed times for CPT codes 11981, 11982, and 11983, however, we do not agree with the AMA RUC recommended work RVUs, and we are finalizing our proposed work RVUs of 1.14 for CPT code 11981, 1.34 for CPT code 11982, and 1.91 for CPT code 11983. For CPT codes 20700 to 20705, we agree with and are finalizing the AMA RUC's recommended work RVUs of 1.50 for CPT code 20700, 1.13 for CPT code 20701, 2.50 for CPT code 20702, 1.80 for CPT code 20703, 2.60 for CPT code 20704, and 2.15 for CPT code 20705. We recognize that the manual preparation and insertion of drug delivery device(s) should take more time than their removal code counterparts, and while we accepted the work RVUs for the removal codes, on the whole, they did not make as much sense in their relativity to each other, with our proposed work RVUs for the insertions. The AMA RUC recommended insertion work RVUs are a better fit with the removal work RVUs.

(3) Bone Biopsy Trocar-Needle (CPT Codes 20220 and 20225)

In October 2017, CPT code 20225 (*Biopsy, bone, trocar, or needle; deep (e.g., vertebral body, femur)*) was identified as being performed by a different specialty than the one that originally surveyed this service. CPT code 20220 (*Biopsy, bone, trocar, or needle; superficial (e.g., ilium, sternum, spinous process, ribs)*) was added as part of the family, and both codes were surveyed and reviewed for the January 2019 RUC meeting.

We disagree with the RUC-recommended work RVU of 1.93 for CPT code 20220 and we proposed a work RVU of 1.65 based on a crosswalk to CPT code 47000 (*Biopsy of liver, needle; percutaneous*). CPT code 47000 shares the same intraservice time of 20 minutes with CPT code 20220 and has slightly higher total time at 55 minutes as compared to 50 minutes. It is also one of the top reference codes selected by the survey respondents. In our review of CPT code 20220, we noted that the recommended intraservice time is decreasing from 22 minutes to 20 minutes (9 percent reduction), and that the recommended total time is increasing from 49 minutes to 50 minutes (2 percent increase). However, the RUC-recommended work RVU is increasing from 1.27 to 1.93, which is an increase of 52 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, changes in surveyed work time should be appropriately reflected in the proposed work RVUs.

In the case of CPT code 20220, we believe that it was more accurate to propose a work RVU of 1.65, based on a crosswalk to CPT code 47000, to account for the decrease in the surveyed intraservice work time. We believe that the work carried out by the practitioner in CPT code 47000 is potentially more intense than the work performed in CPT code 20220, as the reviewed code is a superficial bone biopsy as opposed to the non-superficial biopsy taking place on an internal organ (the liver) described by CPT code 47000. We also note that the survey respondents considered CPT code 47000 to have similar intensity to CPT code 20220: 50 percent or more of the survey respondents rated the two codes as ''identical'' under the categories of Mental Effort and Judgment, Physical Effort Required, and Psychological Stress, along with a plurality of survey respondents rating the two codes as identical in the category of Technical Skill Required. We believe that this provides further support for our belief that CPT code 20220 should be crosswalked to CPT code 47000 at the same work RVU of 1.65.

We disagree with the RUC-recommended work RVU of 3.00 for CPT code 20225 and we proposed a work RVU of 2.45 based on a crosswalk to CPT code 30906 (*Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; subsequent*). CPT code 30906 shares the same intraservice time of 30 minutes and has 1 fewer minute of total time as compared to CPT code 20225. When reviewing this code, we observed a pattern similar to what we had seen with CPT code 20220. We note that the recommended intraservice time for CPT code 20225 is decreasing from 60 minutes to 30 minutes (50 percent reduction), and the recommended total time is decreasing from 135 minutes to 64 minutes (53 percent reduction); however, the RUC-recommended work RVU is increasing from 1.87 to 3.00, which is an increase of about 60 percent. As we noted earlier, we do not believe that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, and we did not propose a linear decrease in the work valuation based on these time ratios. Indeed, we agree with the RUC recommendation that the work RVU of CPT code 20225 should increase over the current valuation. However, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in changes to the work RVUs, and we do not believe that it would be accurate to propose the recommended work RVU of 3.00 given

the significant decreases in surveyed work time.

Instead, we believe that it would be more accurate to propose a work RVU of 2.45 for CPT code 20225 based on a crosswalk to CPT code 30906. We note that this proposed work RVU is a very close match to the intraservice time ratio between the two codes in the family; we proposed a work RVU of 1.65 for CPT code 20220 with 20 minutes of intraservice work time, and a work RVU of 2.45 for CPT code 20225 with 30 minutes of intraservice work time. (The exact intraservice time ratio calculates to a work RVU of 2.47.) We believe that the proposed work RVUs maintain the relative intensity of the two codes in the family, and better preserve relativity with the rest of the codes on the PFS.

For the direct PE inputs, we proposed to replace the bone biopsy device (SF055) supply with the bone biopsy needle (SC077) in CPT code 20225. We note that this code currently makes use of the bone biopsy needle, and there was no rationale provided in the recommended materials to explain why it would now be typical for the bone biopsy needle to be replaced by the bone biopsy device. We proposed to maintain the use of the current supply item. We are also proposing to adopt a 90 percent utilization rate for the use of the CT room (EL007) equipment in CPT code 20225. We previously finalized a policy in the CY 2010 PFS final rule (74 FR 61754 through 61755) to increase the equipment utilization rate to 90 percent for expensive diagnostic equipment priced at more than $1 million, and specifically cited the use of CT and MRI equipment which would be subject to this utilization rate.

We received public comments on the proposed valuation of the codes in the Bone Biopsy Trocar-Needle family. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the CMS proposed work RVU of 1.65 for CPT code 20220 and stated that CMS should instead finalize the RUC-recommended work RVU of 1.93. Commenters stated that a superficial bone biopsy as described in CPT code 20220 is more intense to perform than a liver biopsy as described in the CMS crosswalk code (47000), and that the typical indication for CPT code 20220, a potentially infectious or malignant lesion, requires a biopsy with an 11-gauge Jamshidi bone biopsy needle. Commenters stated that accurate placement and increased risk of adjacent structures results in a greater intensity of physician work relative to CPT code 47000.

Response: We appreciate the additional information from the commenters regarding the relative intensity of CPT codes 20220 and 47000. In light of this additional information, we agree with the commenters that the superficial bone biopsy service described by CPT code 20220 has a higher intensity than the liver biopsy service described by CPT code 47000. Although we stated that the crosswalk code was ''potentially more intense'' in the proposed rule, we ultimately proposed a higher intensity for CPT code 20220 than CPT code 47000 at our work RVU of 1.65. Based on the information provided by the survey respondents, who considered CPT code 47000 to have similar intensity to CPT code 20220, we continue to disagree with the RUC-recommended work RVU of 1.93, which would assign a significantly higher intensity to CPT code 20220. We continue to believe that it was more accurate to propose a work RVU of 1.65, based on the aforementioned crosswalk to CPT code 47000, which assigns both codes a similar intensity, accounts for the decrease in the surveyed intraservice work time, and incorporates the information provided by the survey respondents.

Comment: Several commenters disagreed with the CMS proposed work RVU of 2.45 for CPT code 20225 and stated that CMS should instead finalize the RUC-recommended work RVU of 3.00. Commenters stated that crosswalking a deep bone biopsy performed on patients with a destructive malignant lesion to CPT code 30906, a service used for controlling an established patient's nosebleed, was inappropriate. Commenters noted that the proposed intensity of CPT code 20225 was lower than the intensity of the crosswalk code.

Response: We disagree with the commenters that there is a meaningful difference in intensity between CPT code 20225 and our crosswalk CPT code 30906. These two codes share the same intraservice time of 30 minutes and differ by only 1 minute of total time, 64 minutes as compared to 63 minutes. The intensity of these two codes differs by less than one half of one percentage point, and it would be difficult for two procedures to match more closely on intensity (which is itself a derived number not measured directly) without sharing the same work times. We also disagree with the commenters that the choice of CPT code 30906 is an inappropriate crosswalk on clinical grounds. CPT code 30906 is far from a simple ''nosebleed'', instead describing a service in which the typical patient requires repeated treatment for control of nasal hemorrhages using anesthesia and extensive cautery. Like CPT code 20225, CPT code 30906 is a significant 0-day global procedure that requires 30 minutes of intraservice work time. We continue to believe that it was more accurate to propose a work RVU of 2.45 for CPT code 20225, based on the aforementioned crosswalk to CPT code 30906, which we believe better maintains the relative intensity of the two codes in the family, and better preserves relativity with the rest of the codes on the PFS.

Comment: Several commenters stated the crosswalk or methodology used in the original valuation of CPT code 20220 is unknown and not resource-based, and therefore, it was invalid for CMS to compare the current time and work to the surveyed time and work. Commenters stated that referencing physician times and derived intensities created almost 30 years ago under the Harvard study as a method to critique RUC recommendations was not appropriate. Commenters also stated that when CPT code 20225 was last evaluated in 1995, work times were evaluated with much less rigor, and that the near zero intensity of CPT code 20225 indicated a severely anomalous relationship between the current work value and current physician time.

Response: We disagree with the commenter that it was invalid to compare the current time and work to the surveyed time and work. We believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the CMS proposal to replace the bone biopsy device (SF055) supply with the bone biopsy needle (SC077) in CPT code 20225. Commenters stated that the bone biopsy device was necessary to perform this procedure and that the omission of this supply item when this service was last reviewed in 2004 was an oversight. Commenters stated that in the vast majority of cases, deep bone biopsies are performed percutaneously using a bone biopsy drill device that allows for access to sclerotic bony lesions in a manner that a bone biopsy needle cannot, and that failing to accurately include the devices typically used to perform this service in a nonfacility setting would likely result in the procedures being pushed to a more expensive facility setting.

Response: Although we appreciate the additional information about the bone biopsy device provided by the commenters, we disagree that its use would be typical for CPT code 20225. As we stated in the proposed rule, CPT code 20225 currently makes use of the bone biopsy needle and there was no rationale provided in the recommended materials to explain why it would now be typical for the bone biopsy needle to be replaced by the bone biopsy device. We believe it unlikely that the lack of a bone biopsy device in the current direct PE inputs for CPT code 20225 was an accidental omission, given that it has been omitted from the direct PE inputs for the past 15 years—had this been an oversight, we would expect that there would have been a previous attempt to address it. We also note that the clinical description of work for CPT code 20225 makes no mention of a bone biopsy drill, but does repeatedly mention the use of a needle for the bone biopsy. Based on this evidence, we continue to believe that the continued use of the bone biopsy needle supply would be typical for the procedure.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Bone Biopsy Trocar-Needle family as proposed.

(4) Trigger Point Dry Needling (CPT Codes 20560 and 20561)

For CY 2020, the CPT Editorial Panel approved two new codes to report dry needling of musculature trigger points. These codes were surveyed and reviewed by the HCPAC for the January 2019 RUC meeting.

We disagree with the HCPAC-recommended work RVU of 0.45 for CPT code 20560 (*Needle insertion(s) without injection(s), 1 or 2 muscle(s)*) and we proposed a work RVU of 0.32 based on a crosswalk to CPT code 36600 (*Arterial puncture, withdrawal of blood for diagnosis*). CPT code 36600 shares the identical intraservice time, total time, and intensity with CPT code 20560, which makes it an appropriate choice for a crosswalk. In our review of CPT code 20560, we compared the procedure to the top reference code chosen by the survey participants, CPT code 97140 (*Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes*). This therapy procedure has 50 percent more intraservice time than CPT code 20560, as well as higher total time; however, the recommended work RVU of 0.45 was higher than the work RVU of 0.43 for the top reference code from the survey. We did not agree that CPT code 20560 should be valued at a higher rate, and therefore, we proposed a work RVU of 0.32 based on the aforementioned crosswalk to CPT code 36600.

We disagree with the HCPAC-recommended work RVU of 0.60 for CPT code 20561 (*Needle insertion(s) without injection(s), 3 or more muscle(s)*) and we proposed a work RVU of 0.48 based on a crosswalk to CPT codes 97113 (*Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises*) and 97542 (*Wheelchair management (e.g., assessment, fitting, training), each 15 minutes*). Both of these codes share the same work RVU of 0.48 and the same intraservice time of 15 minutes as CPT code 20561, with CPT code 97113 having two fewer minutes of total time and CPT code 97542 having two additional minutes of total time. We note that this proposed work RVU is an exact match of the intraservice time ratio between the two codes in the family; we proposed a work RVU of 0.32 for CPT code 20560 with 10 minutes of intraservice work time, and a work RVU of 0.48 for CPT code 20561 with 15 minutes of intraservice work time. We also considered crosswalking the work RVU of CPT code 20561 to the top reference code from the survey, CPT code 97140, at a work RVU of 0.43. However, we chose to employ the crosswalk to CPT codes 97113 and 97542 at a work RVU of 0.48 instead, due to the fact that the survey respondents indicated that CPT code 20561 was more intense than CPT code 97140.

We also proposed to designate CPT codes 20560 and 20561 as ''always therapy'' procedures, and we solicited comments on this designation. We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Trigger Point Dry Needling family. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the CMS proposed work RVU of 0.32 for CPT code 20560 and stated that CMS should instead finalize the HCPAC-recommended work RVU of 0.45. Commenters stated that CMS disregarded all factors that go into work valuation apart from time, as well as minimized the understanding of the service on the part of the survey respondents. Commenters stated that the survey respondents recognized that CPT code 20560 is more intense and complex to perform than the top reference code, CPT code 97140, because it is an invasive procedure rather than non-invasive manual therapy. Commenters stated that 70 percent of the survey respondents that selected this key reference code indicated that CPT code 20560 requires more mental effort and judgment and 84 percent indicated that more physiological stress is involved. Commenters stated that noninvasive techniques do not have the same risks or skill requirement as procedures described by 20560, and that a higher level of education for the qualified health care professional is required in addition to a higher level of skill and focus during and following the procedure when performing CPT code 20560.

Response: In response to the first issue raised by the commenters regarding work valuation based on time values, we recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2 of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

We also disagree with the commenters that CPT code 20560 is more intense and complex to perform than the top

reference code, CPT code 97140. Although it is true that a majority of survey respondents stated that CPT code 20560 requires more mental effort/judgment and additional physiological stress, 74 percent of the same survey respondents also stated that CPT code 20560 required less physical effort than CPT code 97140, which would suggest that the reviewed code instead has a lower intensity. We do not agree that the survey responses provide sufficient support for assigning a higher work RVU to CPT 20560 than CPT code 97140, especially given that this top reference code has 50 percent more intraservice time. We similarly do not agree that the intensity of the non-invasive manual therapy procedure described by CPT code 97140 is inherently lower on clinical grounds than the invasive procedure described by CPT code 20560. The manual therapy procedure described by CPT code 97140 has its own distinct type of skill requirements since there is more extensive direct contact between the practitioner and the patient than in CPT code 20560. We continue to believe that CPT code 20560 should not be valued at a higher rate than CPT code 97140, and therefore, we proposed a work RVU of 0.32 based on the aforementioned crosswalk to CPT code 36600.

Comment: Several commenters disagreed with the CMS proposed work RVU of 0.48 for CPT code 20561 and stated that CMS should instead finalize the HCPAC-recommended work RVU of 0.60. Commenters stated that CMS started with the work RVU they assigned to CPT code 20560 and then selected crosswalk codes that matched the intraservice time ratio between the codes in the family. Commenters stated that this is an erroneous methodology and, if finalized, would create a rank order anomaly between this and other similar services.

Response: We clarify that we did not use an intraservice time ratio to determine the work valuation of CPT code 20561. As we stated in the proposed rule, we proposed a work RVU of 0.48 based on a crosswalk to CPT codes 97113 and 97542 as both of these codes share the same work RVU of 0.48 and the same intraservice time of 15 minutes as CPT code 20561, with CPT code 97113 having 2 fewer minutes of total time and CPT code 97542 having 2 additional minutes of total time. We believe that the close match between the surveyed work time for CPT code 20561 and the work times of these two codes indicated that these three services should be valued similarly, and we disagree that the proposed work RVU would create a rank order anomaly due to the close relationship between the work times of these codes. We noted in the proposed rule that the proposed work RVU of 0.48 for CPT code 20561 is an exact match of the intraservice time ratio between the two codes in the family; however, we cited this fact as supporting evidence and not as the primary basis for valuation. Although we did not use a time ratio for work valuation in this case, we continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: Several commenters provided the same rationale for CPT code 20561 in relation to the top reference code from the survey, CPT code 97140, as they had made for CPT code 20560. Commenters stated that the survey respondents recognized that CPT code 20561 is more intense and complex to perform than the top reference code, CPT code 97140, because it is an invasive procedure rather than non-invasive manual therapy. Commenters stated that 71 percent of the survey respondents that selected this key reference code indicated that CPT code 20560 requires more mental effort and judgment and 88 percent indicated that more physiological stress is involved. Commenters stated that noninvasive techniques do not have the same risks or skill requirement as procedures described by 20561, and that a higher level of education for the qualified health care professional is required in addition to a higher level of skill and focus during and following the procedure when performing CPT code 20561.

Response: We continue to disagree with the commenters that CPT code 20561 is more intense and complex to perform than the top reference code, CPT code 97140, for many of the same reasons that we cited in our response to the same comments regarding CPT code 20560. As we observed for the first code in the family, 69 percent of the same survey respondents also stated that CPT code 20561 required less physical effort than CPT code 97140, which would again suggest that the reviewed code instead has a lower intensity. Unlike CPT code 20560, we agree that CPT code 20561 should have a higher work RVU than CPT code 97140, which is why we proposed a work RVU of 0.48 for the procedure. To the extent that the commenters are stating that CPT code 20561 should have a higher work RVU than CPT code 97140, we agree with the commenters and we proposed a work RVU accordingly. We do not agree with the commenters that CPT code 20561 should be valued nearly 50 percent higher than CPT code 97140 given their nearly identical work times and similar overall intensity.

Comment: One commenter agreed with the CMS proposal to designate CPT codes 20560 and 20561 as ''always therapy'' procedures. The commenter stated that acupuncturists would also use additional modalities and procedures in their scope along with these codes, and that these would not typically be billed independently.

Response: We appreciate the support for our proposals from the commenter.

Comment: Many commenters disagreed with the CMS proposal to designate CPT codes 20560 and 20561 as ''always therapy'' procedures. Commenters stated that these services may be performed by a wide range of professionals and that it may not be appropriate to bill the service under a therapy plan of care. Commenters also stated that assigning a designation of ''always therapy'' to these codes would be inconsistent with CMS' designation of other CPT codes as ''sometimes therapy'' codes that could be appropriately provided either as therapy services or non-therapy services. Other commenters objected to the proposal by stating that dry needling codes should be placed in the surgical section of the CPT codebook, and that due to the invasive nature of these procedures using needles, they should only be performed by licensed medical physicians or licensed acupuncturists. Commenters urged CMS to change the designation of CPT codes 20560 and 20561 to ''sometimes therapy'' procedures.

Response: We appreciate the feedback from the commenters in providing additional information about which providers will bill these services, and the fact that it may not be appropriate to bill these service under a therapy plan of care. After consideration of the comments, we are not finalizing our proposal to designate CPT codes 20560 and 20561 as ''always therapy'' procedures. We believe that a ''sometimes therapy'' designation would be more appropriate if we were to designate these codes as therapy procedures.

Comment: One commenter stated that if CPT codes 20560 and 20561 are covered services under Medicare then

an acupuncturist should be a qualified health care professional and should be recognized by Medicare to provide this service. The commenter described some of the clinical benefits associated with acupuncture and stated again that acupuncturists should be recognized by Medicare to provide dry needling.

Response: We appreciate the feedback from the commenter regarding the practice of acupuncture. However, we did not make a proposal regarding the classification of acupuncturists, and therefore, this comment is out of scope.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Trigger Point Dry Needling family as proposed. We are not finalizing these codes as ''always'' or ''sometimes'' therapy services because dry needling services are non-covered unless otherwise specified through a national coverage determination (NCD). Please refer to the NCD Manual, Section 30.3 at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf.*

(5) Closed Treatment Vertebral Fracture (CPT Code 22310)

This service was identified through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes.

For CPT code 22310 (Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing), we disagreed with the recommended work-RVU of 3.75, stating that we did not think that this reduction in work RVU from the current value of 3.89 was commensurate with the RUC-recommended 33-minute reduction in intraservice time and 105-minute reduction in total time. We noted that while we understand that the RUC considers the current Harvard study time values for this service to be invalid estimations, we believed that a further reduction in work RVUs is warranted given the significance of the RUC-recommended reduction in physician time. We proposed a work RVU of 3.45 with a crosswalk to CPT code 21073 (*Manipulation of temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (i.e., general or monitored anesthesia care)*), which has an identical intraservice time and similar total time as those proposed by the RUC for CPT code 22310 to more accurately account for the decrease in the surveyed work time.

For the direct PE inputs, we proposed to refine the equipment time for the power table (EF031) to conform to our established policies for non-highly technical equipment.

We received public comments on the proposed valuation of the codes in the Closed Treatment Vertebral Fracture family. The following is a summary of the comments we received and our responses.

Comment: A few commenters stated that CMS is inappropriately comparing accurate survey time to Harvard time, which the commenter stated holds zero validity for comparison. The commenters further stated that our proposed value fails to acknowledge that the Harvard work value was much higher based on the Harvard study physician work times than the current work value of the service. One commenter noted that in the June 1991 proposed rule, the work RVU for 22310, based on the Harvard study, was 6.31, then, in the November 1991 final rule for the 1992 PFS, the work RVU was reduced to 1.95, and then in 1997, hospital and office visits were assigned by algorithm for practice expense (PE) purposes. The commenter stated that the entire history of value of this code is fraught with misestimations of time and the current work RVU of 3.89 has nothing to do with the Harvard study.

Response: We believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

We recognize that this code has undergone revisions and that the work value has changed significantly from the Harvard value. If we accept the commenter's contention that the current work RVU is unrelated to the original Harvard work RVU, and we compare the time values to the original 1991 Harvard work value of 6.31, our proposed work RVU continues to appear to be appropriate. A ratio of the change in intraservice time to the original RVU of 6.31 is 3.50; a ratio of the change in total time to the original work RVU of 6.31 is 2.38. These ratios suggest that our proposed RVU of 3.45 is a more accurate valuation than the RUC's recommended RVU of 3.75. We continue to believe that a crosswalk to CPT code 21073, which describes manipulation under general or monitored care under anesthesia with manipulation of the TMJ, is appropriate. CPT code 22310 involves closed treatment without manipulation and the application of a brace, while CPT code 21073 involves anesthesia and manipulation; we believe the similar work and time of CPT code 21073 validates our work RVU of 3.45 for CPT Code 22310.

Comment: Several commenters stated that they agreed with our proposal to refine the equipment time for the power table (EF031) to conform to our established policies for non-highly technical equipment.

Response: We appreciate the support for our proposal from the commenters.

After consideration of the public comments, we are finalizing our work RVU of 3.45 as proposed. We are also finalizing the direct PE inputs as proposed.

(6) Tendon Sheath Procedures (CPT Codes 26020, 26055, and 26160)

The RUC identified these services through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. For CPT code 26020 (Drainage of tendon sheath, digit and/or palm, each), we do not agree with the RUC-recommended work RVU of 7.79 based on the survey median. While we agree that the survey data validate an increase in work RVU, we see no compelling reason that this service would be significantly more intense to furnish than services of similar time values. Therefore, we proposed a work RVU of 6.84 which is the survey 25th percentile. As further support for this value, we note that it falls between the work RVUs of CPT code 28122 (*Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus*), with a work RVU of 6.76, and CPT code 28289 (*Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant*), with a work RVU of 6.90; both codes have intraservice time values that are identical to, and total time values

that are similar to, the RUC-recommended time values for CPT code 26020.

For CPT code 26055 (*Tendon sheath incision (e.g., for trigger finger)*), we do not agree with the RUC recommendation to increase the work RVU to 3.75 despite a reduction in physician time. Instead, we proposed to maintain the current work RVU of 3.11; we are supporting this based on a total time increment methodology between the CPT code 26020 and CPT code 26055. The total time ratio between the recommended time of 119 minutes and the recommended 262 minutes for code 26020 equals 45 percent, and 45 percent of our proposed RVU of 6.84 for CPT code 26020 equals a work RVU of 3.10, which we believe validates the current work RVU of 3.11. We proposed the RUC-recommended work RVU of 3.57 for CPT code 26160 (*Excision of lesion of tendon sheath or joint capsule (e.g., cyst, mucous cyst, or ganglion), hand or finger*). We note that our proposed work RVUs validate the RUC's contention that CPT code 26160 is slightly more intense to perform than CPT code 26055.

For the direct PE inputs, we proposed to refine the quantity of the impervious staff gown (SB027) supply from 2 to 1 for CPT codes 26055 and 26160. We believe that the second impervious staff gown supply is duplicative due to the inclusion of this same supply in the surgical cleaning pack (SA043). The recommended materials state that a gown is worn by the practitioner and one assistant, which are provided by one standalone gown and a second gown in the surgical cleaning pack.

We received public comments on the proposed valuation of the codes in the Tendon Sheath Procedures family. The following is a summary of the comments we received and our responses.

Comment: A few commenters stated that, for CPT code 26020, our supporting reference codes, CPT code 28122 and CPT code 28289, are inappropriate in that they have lower total time values than the surveyed total time of CPT code 26020, and that this reflects that these two reference codes typically involve a patient who is discharged within 23 hours of the procedure and are less intense. The commenter stated that the RUC's recommendation of the median survey value for CPT code 26020 is necessary because even at the survey median, the intraoperative intensity (0.027), is so low that there are no comparator codes with a lower work RVU. This commenter also stated that the survey 25th percentile work RVU would vastly underestimate the physician work, resulting in an intraoperative intensity of 0.006—or essentially zero.

Response: For CPT code 26020, we continue to believe that the RUC's recommended work RVU of 7.79 is disproportionately high, as it represents a 35 percent increase in work despite a 5 minute increase in intraservice time and a 30 minute increase in total time. We believe our proposal to value CPT code 26020 with the survey 25th percentile, which represents a roughly 26 percent increase is more proportionate. Further, we note that our proposed value recognizes the work inherent in this procedure, including the requisite inpatient monitoring, as it lies within the top quartile of all 90-day global period codes with an intraservice time of 45 minutes. We recognize that the relatively high total time value for this code results in a relatively low intensity value, however we continue to believe that our value appears to be consistent with other relatively low-intensity procedures of similar times. The intensity value that results from our proposed work RVU is extremely close to that which results from the RUC's recommended work RVU, and therefore, we continue to think that our value adequately reflects the work inherent in the procedure.

Comment: One commenter stated that our proposal to maintain the current work RVU for CPT code 26055 indicates that we inappropriately noted that the reduction in time should exactly correlate with a reduction in work RVU. The current times are based on a 2005 survey but the current work RVU is based on the Harvard study. The commenter stated that CMS should not compare the old times relative to the work RVU. The commenter disagreed with use of an incremental methodology to value CPT code 26055, as it inaccurately treats all components of the physician time as having identical intensity. In addition, the commenter stated maintaining the current work RVU for CPT code 26055 results in an inappropriately low intensity of 0.011 which does not reflect an open surgical procedure typically performed in a facility under moderate sedation and is not much higher than the assigned value for pre-service scrub/dress/wait time.

Response: We do not believe that our proposal assumes that the reduction in time for this service should exactly correlate with a reduction in work RVU; a proportionate reduction based solely on time would result in a lower RVU than that proposed. As discussed elsewhere in this rule, we believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277). We continue to believe that our proposed work RVU maintains the proportionate relationship with CPT code 26020.

We continue to believe that comparisons to similar procedures of similar time values indicate that our proposed value accurately reflects the intensity inherent in the procedure.

Comment: Several commenters disagreed with the CMS proposal to refine the quantity of the impervious staff gown (SB027) supply from 2 to 1 for CPT codes 26055 and 26160 and stated that this gown was not duplicative. Commenters stated that two gowns are required in the procedure room (for the practitioner and a clinical staff member) and a separate gown is required, typically for a second clinical staff individual, for the cleaning of instruments in a separate room. Commenters stated that the US Department of Labor, Occupational Safety and Health Administration (OSHA) regulations require that all personal protective equipment must be removed prior to leaving the work area, which includes removing the impervious staff gown worn during the procedure, and therefore, necessitating the inclusion of another gown as a supply input.

Response: We appreciate the additional information provided by the commenters regarding the number of impervious staff gowns typically used in these procedures. As a result of this additional information, we are not

finalizing our proposed refinement to reduce the quantity of the impervious staff gown (SB027) supply from 2 to 1 for CPT codes 26055 and 26160. We are instead finalizing the RUC-recommended direct PE inputs for all three codes in the family.

After consideration of the public comments, we are finalizing our proposed work RVUs of 6.84 for CPT code 26020, 3.11 for CPT code 26055, and 3.57 for CPT code 26160. We are finalizing the RUC-recommended direct PE inputs for all three codes in the family as stated previously.

(7) Closed Treatment Fracture—Hip (CPT Code 27220)

This service was identified through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. For CPT code 27220 (*Closed treatment of acetabulum (hip socket) fracture(s); without manipulation*), we disagree with the RUC-recommended work RVU of 6.00 based on the survey median value, because we do not believe that this reduction in work RVU from the current value of 6.83 is commensurate with the RUC-recommended a 19-minute reduction in intraservice time and an 80-minute reduction in total time. While we understand that the RUC considers the current Harvard study time values for this service to be invalid estimations, we believe that a further reduction in work RVUs is warranted given the significance of the RUC-recommended reduction in physician time. We believe that it would be more accurate to propose the survey 25th percentile work RVU of 5.50, and we are supporting this value with a crosswalk to CPT code 27267 (*Closed treatment of femoral fracture, proximal end, head; without manipulation*) to account for the decrease in the surveyed work time.

For the direct PE inputs, we proposed to refine the equipment time for the power table (EF031) to conform to our established policies for non-highly technical equipment.

We received public comments on the proposed valuation of the Closed Treatment Fracture—Hip code. The following is a summary of the comments we received and our responses.

Comment: A few commenters disagreed with our proposal, stating that it relies on a comparison of accurate survey time to Harvard time, the latter of which they stated holds zero validity for comparison.

Response: We believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: One commenter stated that reducing the work RVU of this service based on a comparison to the current work value does not adequately take into account that the current value reflects adjustments made to the original Harvard work RVU in various rule cycles over many years to account for increases in the E/M services included in the global period of this service. A downward adjustment to the work RVU would essentially reverse increases that have been made to account for this post-operative work.

Response: We disagree that reducing the work RVU ignores the value of the E/M services included in the global period; while the Harvard work values for services such as this one have been adjusted upward in previous years to account for these services, we nevertheless have included the surveyed work time in our analysis of this code; and this surveyed time includes post-operative work. Our proposed work RVU was not based solely on the reduction in time. We note that our crosswalk code, CPT code 27267 (*Closed treatment of femoral fracture, proximal end, head; without manipulation*) includes a similar amount of postoperative work, and therefore, we believe that our value adequately reflects this work.

Comment: The RUC commented that our proposed work RVU will inappropriately value this service equally to the work RVU of the survey key reference service, CPT code 27267, and the latter has significantly less pre-service time, and is thus not an appropriate crosswalk. Furthermore, our proposed value does not adequately correct the negative IWPUT resulting from the current value, stating that the resulting IWPUT of 0.008 is essentially zero.

Response: We continue to believe that CPT code 27267 is an appropriate crosswalk; both procedures involve closed treatment of hip without manipulation. While the derived intensity value that results from our proposed value of 5.50 is lower than that which results from the RUC's value, it is only negligibly so, with a difference of 0.033 in IWPUT.

Comment: A commenter stated that they agreed with our proposal to refine the equipment time for the power table (EF031) to conform to our established policies for non-highly technical equipment.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing as proposed a work RVU of 5.50 for CPT code 27220. We are also finalizing the direct PE inputs as proposed.

(8) Arthrodesis—Sacroiliac Joint (CPT Code 27279)

In the CY 2018 PFS final rule (82 FR 53017), CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) was nominated for review by stakeholders as a potentially misvalued service. We stated that CPT code 27279 is potentially misvalued, and that a comprehensive review of the code values was warranted. This code was subsequently reviewed by the RUC. According to the specialty societies, the previous 2014 survey of CPT code 27279, was based on flawed methodology that resulted in an underestimation of intraoperative intensity. When CPT code 27279 was surveyed in 2014, there was a low rate of response. Due to the dearth of survey data and the RUC's agreement with the specialty society at the time that the survey respondents had somewhat overvalued the work involved in performing this service, the RUC used a crosswalk to CPT code 62287 (*Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar*) to recommend a work RVU of 9.03. The

specialty societies indicated that with increased and broader utilization of this technique, the 2018 survey is a more robust assessment of physician work and intensity and provides more data with which to make a crosswalk recommendation. According to the RUC, there is no compelling evidence that the physician work, intensity or complexity has changed for this service.

We proposed to maintain the current work RVU of 9.03 as recommended by the RUC. A stakeholder stated that maintaining this RVU would constitute the continued undervaluation of this service, and that this would incentivize use of a more intensive and invasive procedure, CPT code 27280 (*Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed*), as well as incentivize this service to be inappropriately furnished on an inpatient basis. This stakeholder has requested that, in the interest of protecting patient access, we implement payment parity between the two services by proposing to crosswalk the work RVU of CPT code 27279 to that of CPT code 27280, which has a work RVU of 20.00. While we proposed the RUC-recommended work RVU, we solicited public comment on whether an alternative valuation of 20.00 would be more appropriate. This alternative valuation would recognize relative parity between these two services in terms of the work inherent in furnishing them.

We proposed the RUC-recommended direct PE inputs for CPT code 27279.

We received public comments on the proposed valuation of the Arthrodesis—Sacroiliac Joint code. The following is a summary of the comments we received and our responses.

Comment: A commenter questioned how the most recent stakeholder comment was obtained, since the RUC recommendations are not public until after the publication of the proposed rule. The commenter stated that the recent stakeholder comment could not have been received by CMS via the formal comment process, and questioned if the comment was communicated via the passing of verbal comment between individuals at the RUC meeting or someone gained confidential information inappropriately. The commenter stated the reason this service was reviewed in 2019 is because it was nominated by a stakeholder that it may be undervalued.

Response: This communication between the agency and a stakeholder was not inappropriate. When considering potential valuation for services on the PFS, we may take into account information provided to us by stakeholders including specialty societies that may have participated in the RUC process but did not agree with what was submitted as part of the RUC's recommendations. In any event, we reiterate that the stakeholder's argument that the service is undervalued refers to the current valuation of the service.

Comment: The RUC restated that it had determined that there is not compelling evidence to revalue this procedure as the intensity required to perform CPT code 27279 has not changed. With no convincing rationale that the physician work, intensity or complexity has changed for this service, the RUC recommended to maintain the work RVU of 9.03 for CPT code 27279. The RUC did not believe that CPT code CPT code 27279 should be valued with a direct crosswalk to CPT code 27280, stating that the latter is vastly different than CPT code 27279 because it is an open procedure that includes instrumentation, requires double the amount of intra-service time to perform, and is more intense and complex to perform.

Many commenters stated that the work RVU of CPT code 27279 is undervalued, and stated that the service is complex and intense and involves significant risk and preoperative work. Commenters presented study results that demonstrate the advantages of this procedure over the open procedure, stating that it is minimally invasive and has vastly improved outcomes. Some commenters cited studies that they noted demonstrate cost-effectiveness metrics and patient reported outcome improvements that are better than nearly all orthopaedic and spinal procedures, and more cost-efficient than ongoing nonoperative care. Commenters stated that, while the procedure described by CPT code 27279 is less invasive than the open procedure; it nevertheless is similar in terms of intensity, as it requires significant pre and postoperative care, image guidance, and monitoring. A commenter cited risk associated with placement of the guide wires which may result in damage to vital structures including spinal nerve roots, blood vessels, and viscera. Similarly, commenters cited risks inherent in spinal procedures such as bleeding, infection, and pseudoarthrosis. One commenter discussed insertion of pins and pegs that run the risk of violating the sacral foraminas creating radiculopathies. In addition, a commenter mentioned the potential for postoperative hematomas. Other risks cited include considerable risk of nerve damage, vascular compressions and iatrogenic fractures caused by misplacement of the guide wires, broaches and large implants. According to a commenter, the anatomy involved in this procedure is more complex than for a discectomy or decompression laminectomy. Commenters stated that the procedure is significantly more intense than the crosswalk code that its current value was originally based on, CPT code 62287 (*Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar*). The commenters stated that this procedure requires special skill given the complexity of the anatomy and extensive preoperative time.

Commenters offered various suggestions for a more appropriate valuation for CPT code 27279; many commenters stated that 27279 is more appropriately valued with a work RVU of 20.00, as it is comparable in time and intensity to CPT code 27280. One commenter suggested a work RVU of 14.23 which resulted from a regression analysis of surveys. Other suggested crosswalk codes offered by commenters include CPT codes 63030 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar*), with a work RVU of 13.18, 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar*), with a work RVU of 15.37, 22551 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2*), with a work RVU of 25.00, 27245 (*Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage*) with a work RVU of 18.18, 27130 (*Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft*), with a work RVU of 20.72, 22612 (*Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)*) with a

work RVU of 23.53, 63040 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical*) with an RVU of 20.31, 63042 (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar*) with an RVU of 18.76, 63045 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; cervical*) with a work RVU of 17.95, and 63046 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; thoracic*) with a work RVU of 17.25.

Response: Commenters have provided extensive evidence that leads us to believe that the current work RVU understates the inherent intensity of the procedure. We agree with the RUC's longstanding contention that survey data is critical in determining appropriate valuation of services. The fact that this code is valued based on a crosswalk from 2014 rather than on updated survey data raised concerns. The RUC's survey data, as well as extensive stakeholder comment indicates to us that this service continues to be undervalued.

We agree with the RUC that CPT code 27279 would not be accurately valued identically to the analogous open procedure CPT code 27280, as the latter is substantially more complex and requires twice the amount of intraservice time to perform. Therefore, finalizing an equivalent value for these two services would introduce a rank-order anomaly. While we are persuaded by extensive public comment that this service as currently valued does not adequately reflect the work inherent in performing the procedure, we note that all of the crosswalk codes recommended by commenters involve significantly more physician time than that required for CPT code 27279, and values crosswalked to these codes would not maintain appropriate rank-order between CPT codes 27279 and 27280, and would in many instances result in a valuation that is higher than that of the open procedure, CPT code 27280. We believe it is preferable to value this service in close adherence to the surveyed time values. After consideration of the comments, we are finalizing a work RVU of 12.13 with a direct crosswalk to CPT code 57288 (*Sling operation for stress incontinence (e.g., fascia or synthetic)*), which describes an open procedure of similar intensity. This procedure has an identical intraservice time value and similar total time value. We believe that the description of this service and its work and time values indicate that it is a strong crosswalk and a work RVU of 12.13 is a more accurate valuation for this service. We believe a value crosswalked to this service more accurately reflects the work inherent in performing the procedure while accounting for the surveyed work time.

After consideration of the public comments, we are finalizing a work RVU of 12.13 for this service. We are also finalizing the direct PE inputs as proposed.

(9) Pericardiocentesis and Pericardial Drainage (CPT Code 33016, 33017, 33018, and 33019)

CPT code 33015 (*Tube pericardiostomy*) was identified as potentially misvalued on a Relativity Assessment Workgroup (RAW) screen of codes with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS or other source codes. In September 2018, the CPT Editorial Panel deleted four existing codes and created four new codes to describe pericardiocentesis drainage procedures to differentiate by age and to include imaging guidance.

We proposed to refine the work RVU for all four codes in the family. We disagree with the RUC-recommended work RVU of 5.00 for CPT code 33016 (*Pericardiocentesis, including imaging guidance, when performed*) and proposed a work RVU of 4.40 based on a crosswalk to CPT code 43244 (*Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices*). CPT code 43244 shares the same intraservice time of 30 minutes with CPT code 33016 and has a slightly longer total time of 81 minutes as compared to 75 minutes for the reviewed code. In our review of CPT code 33016, we noted that the recommended intraservice time as compared to the current initial pericardiocentesis procedure (CPT code 33010) is increasing from 24 minutes to 30 minutes (25 percent), and the recommended total time is remaining the same at 75 minutes; however, the RUC-recommended work RVU is increasing from 1.99 to 5.00, which is an increase of 151 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, modest increases in time should be appropriately reflected with a commensurate increase the work RVUs. We also conducted a search in the RUC database among 0-day global codes with 30 minutes of intraservice time and comparable total time of 65–85 minutes. Our search identified 49 codes and all 49 of these codes had a work RVU lower than 5.00. We do not believe that it would serve the interests of relativity to establish a new maximum work RVU for this range of time values.

As a result, we believe that it is more accurate to propose a work RVU of 4.40 for CPT code 33016 based on a crosswalk to CPT code 43244 to account for these modest increases in the surveyed work time as compared to the predecessor pericardiocentesis codes. We are aware that CPT code 33016 is bundling imaging guidance into the new procedure, which was not included in the previous pericardiocentesis codes. However, we do not believe that the recoding of the services in this family has resulted in an increase in their intensity, only a change in the way in which they will be reported, and therefore, we do not believe that it would serve the interests of relativity to propose the RUC-recommended work values for all of the codes in this family. We also note that, through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular servicers. For example, a practitioner would not be carrying out the full preservice work twice for CPT codes 33010 and 76930, but preservice times were assigned to both codes under the old coding. We believe the new coding assigns more accurate work times, and thus, reflects efficiencies in resource costs that existed but were not reflected in the services as they were previously reported. If the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which were largely unchanged from the predecessor codes.

We disagree with the RUC-recommended work RVU of 5.50 for CPT code 33017 (*Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy*

and/or ultrasound guidance, when performed; 6 years and older without congenital cardiac anomaly) and proposed a work RVU of 4.62 based on a crosswalk to CPT code 52234 (*Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; SMALL bladder tumor(s) (0.5 up to 2.0 cm)*). CPT code 52234 shares the same intraservice time of 30 minutes with CPT code 33017 and has 2 additional minutes of total time at 79 minutes as compared to 77 minutes for the reviewed code. In our review of CPT code 33017, we noted many of the same issues that we had raised with CPT code 33016, in particular with the increase in the work RVU greatly exceeding the increase in the surveyed work times as compared to the predecessor pericardiocentesis codes. We searched the RUC database again for 0-day global codes with 30 minutes of intraservice time and comparable total time of 67–87 minutes. Our search identified 43 codes and again all 43 of these codes had a work RVU lower than 5.50. As we stated with regard to CPT code 33016, we do not believe that it would serve the interests of relativity to establish a new maximum work RVU for this range of time values. We believe that it is more accurate to propose a work RVU of 4.62 for CPT code 33017 based on a crosswalk to CPT code 52234 based on the same rationale that we detailed with regards to CPT code 33016.

We disagree with the RUC-recommended work RVU of 6.00 for CPT code 33018 (*Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; birth through 5 years of age, or any age with congenital cardiac anomaly*) and proposed a work RVU of 5.00 based on the survey 25th percentile value. In our review of CPT code 33018, we noted many of the same issues that we had raised with CPT codes 33016 and 33017, in particular with the increase in the work RVU greatly exceeding the increase in the surveyed work times as compared to the predecessor pericardiocentesis codes. The recommended work RVU of 6.00 was based on a crosswalk to CPT code 31603 (*Tracheostomy, emergency procedure; transtracheal*), which shares the same intraservice time of 30 minutes with CPT code 33018 and very similar total time. While we agree that CPT code 31603 is a close match to the surveyed work times for CPT code 33018, we do not believe that it is the most accurate choice for a crosswalk due to the fact that CPT code 31603 is a clear outlier in work valuation. We searched for 0-day global codes in the RUC database with 30 minutes of intraservice time and a comparable 90–120 minutes of total time. There were 21 codes that met this criteria, and the recommended crosswalk to CPT code 31603 had the highest work RVU of any of these codes at the recommended 6.00. Furthermore, there was only one other code with a work RVU above 5.00, another tracheostomy procedure described by CPT code 31600 (Tracheostomy, planned (separate procedure)) at a work RVU of 5.56. None of the other codes had a work RVU higher than 4.69, and the median work RVU of the group comes out to only 4.00. The two tracheostomy procedures have work RVUs more than a full standard deviation above any of the other codes in this group of 0-day global procedures.

We do not mean to suggest that the work RVU for a given service must always fall in the middle of a range of codes with similar time values. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. However, we also do not believe that it would serve the interests of relativity by crosswalking the work RVU of CPT code 33018 to tracheostomy procedures that are higher than anything else in this group of codes, procedures that we believe to be outliers due to the serious risk of patient mortality associated with their performance. We believe that it is this patient risk which is responsible for the otherwise anomalously high intensity in CPT codes 31600 and 31603. Therefore, we proposed a work RVU of 5.00 for CPT code 33018 based on the survey 25th percentile, which we believe more accurately captures both the time and intensity associated with the procedure.

We disagree with the RUC-recommended work RVU of 5.00 for CPT code 33019 (*Pericardial drainage with insertion of indwelling catheter, percutaneous, including CT guidance*) and proposed a work RVU of 4.29 based on the survey 25th percentile value. In our review of CPT code 33019, we noted many of the same issues that we had raised with CPT codes 33016–33018, in particular with the increase in the work RVU greatly exceeding the increase in the surveyed work times as compared to the predecessor pericardiocentesis codes. We searched for 0-day global codes in the RUC database with 30 minutes of intraservice time (slightly higher than the 28 minutes of intraservice time in CPT code 33019) and a comparable 70–100 minutes of total time. Our search identified 45 codes and again all 45 of these codes had a work RVU lower than 5.00, which led us to believe that the recommended work RVU for CPT code 33019 was overvalued. We also compared CPT code 33019 to the most similar code in the family, CPT code 33017, and noted that the survey respondents indicated that CPT code 33019 should have a lower work RVU at both the survey 25th percentile and survey median values. Therefore, we proposed a work RVU of 4.29 for CPT code 33019 based on the survey 25th percentile value. We are supporting this proposal with a reference to CPT code 31254 (*Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)*), a recently-reviewed code with an intraservice work time of 30 minutes, a total time of 84 minutes, and a work RVU of 4.27.

The RUC did not recommend and we did not propose any direct PE inputs for the codes in this family.

We received public comments on the proposed valuation of the codes in the Pericardiocentesis and Pericardial Drainage family. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated the crosswalk or methodology used in the original valuation of CPT code 33015 is unknown and not resource-based, and therefore, it was invalid for CMS to compare the current time and work to the surveyed time and work of the newly created codes in the family. Commenters also stated since CPT codes 33010 and 33015 were last valued, there has been a change in the patient population; patients who receive these services have become more complex, acute, and heterogeneous. Commenters stated that several of these deleted codes being bundled into the new codes have negative intensities, which indicated a very anomalous relationship between the current work RVUs and the current work times.

Response: We disagree with the commenter that it was invalid to compare the current time and work to the surveyed time and work. We believe it is crucial that the code valuation process take place with the understanding that the existing work times used in the PFS ratesetting processes are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward

process and that the intensity associated with changes in time is not necessarily always linear. That is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the CMS proposed work RVU of 4.40 for CPT code 33016 and stated that CMS should instead finalize the RUC-recommended work RVU of 5.00. Commenters stated that CPT code 33016 is one of the more intense procedures that interventional cardiologists perform, with two of the most common complications being either lacerating the coronary artery or puncturing the right ventricle, either of which can be fatal. Commenters stated that the reduction in intensity for CPT code 33016 proposed by CMS would establish this service out of rank order with other services in the PFS, including the proposed crosswalk code. Commenters stated that the upper endoscopy service described by CPT code 43244 involves less work and less risk than performing CPT code 33016, even considering that the typical patient for CPT code 43244 presents with hematemesis, and therefore, it is not an appropriate crosswalk.

Response: We agree with the commenters that CPT code 33016 is a highly intense procedure with life-threatening risks to the patient. This is the reason we crosswalked the work RVU to CPT code 43244, a similarly high intensity Esophagogastroduodenoscopy procedure that involves inserting a flexible upper endoscope through the mouth and esophagus into the proximal stomach, then insufflating the stomach with air after suctioning its liquid contents to perform an examination of the entire stomach in the forward and retroflexed position. We note as well that our proposed work RVU of 4.40 for CPT code 33016 results in a higher intensity for the code than for CPT code 43244. We agree with the commenters that CPT code 33016 should have the higher intensity between the two codes, which is what we proposed.

We also mentioned in the proposed rule that we had conducted a search in the RUC database among 0-day global codes with 30 minutes of intraservice time and comparable total time of 65–85 minutes. We mentioned that our search identified 49 codes and all 49 of these codes had a work RVU lower than the recommended 5.00. We add that out of those 49 codes identified by our search, only 3 of them had a work RVU higher than the proposed 4.40: CPT code 37191 (*Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed*) at a work RVU of 4.46, CPT code 45385 (*Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique*) at a work RVU of 4.57, and CPT code 52234 (*Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; SMALL bladder tumor(s) (0.5 up to 2.0 cm)*) at a work RVU of 4.62. Our proposed valuation for CPT code 33016 recognizes the dangerous nature of the procedure and places it above the 90th percentile of the distribution of codes with similar work times. However, as we stated in the proposed rule, we do not believe that it would serve the interests of relativity to establish a new maximum work RVU that goes beyond this range of time values. We do not believe that the recoding of the services in this family has resulted in an increase in their intensity, only a change in the way in which they will be reported, and through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular servicers. We believe the new coding assigns more accurate work times, and thus, reflects efficiencies in resource costs that existed but were not reflected in the services as they were previously reported. If the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which were largely unchanged from the predecessor codes.

Comment: Several commenters disagreed with the CMS proposed work RVU of 4.62 for CPT code 33017 and stated that CMS should instead finalize the RUC-recommended work RVU of 5.50. Commenters stated that CPT code 52234 was not an appropriate crosswalk code as it is a planned procedure, whereas code 33017 is typically emergent and more intense as the patient has acute hemodynamic instability.

Response: We disagree with the commenters that CPT code 52234 is not an appropriate crosswalk code on the grounds that it is a planned procedure. We continue to believe that the nature of the PFS relative value system is that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. To the extent that commenters stated that CPT code 33017 is a more intense procedure than CPT code 52234, we agree with the commenters, which is why we proposed a higher intensity for CPT code 33017 in the proposed rule.

Comment: Several commenters stated that the proposed work RVU increment between CPT codes 33016 and 33017 (0.22) does not align with the relative increased difficulty and additional work involved in performing CPT code 33017. Commenters stated that CPT code 33017 includes all work of CPT code 33016, with the addition of suturing an indwelling catheter in place, as well as the work of managing that catheter, and is an emergent procedure as opposed to a planned procedure. Commenters stated that the intensity of the proposed value for CPT code 33017 is only 5 percent higher than CPT code 33016, and that this would be insufficient.

Response: We agree with the commenters that CPT code 33017 is a more intense procedure than CPT code 33016, which is why we proposed a higher intensity for this emergent procedure. However, we do not agree with the commenters that this greater intensity justifies the RUC-recommended work increment of 0.50 work RVUs between the two procedures. We believe that if CPT code 33017 typically required a significant amount of additional work in comparison to CPT code 33016, it would have been reflected in the surveyed work times for the two procedures. Instead, the surveyed work times are nearly identical between the two procedures, with the same intraservice time and only 2 additional minutes of total time for CPT code 33017, 77 minutes in comparison to 75 minutes. Absent evidence of additional work time from the survey respondents,

we continue to believe that the proposed work RVU and proposed intensity for CPT code 33017 accurately capture the increased difficulty of the procedure in comparison to CPT code 33016.

Comment: Several commenters disagreed with the CMS proposed work RVU of 5.00 for CPT code 33018 and stated that CMS should instead finalize the RUC-recommended work RVU of 6.00. Commenters stated that the typical patient for CPT code 33018 is a small child, and that since there is less space for fluid to accumulate in a small child, the target-zone is smaller for the needle, and therefore, the procedure is more intense than the other codes in the family. Commenters stated that the proposed intensity of CPT code 33018 is nearly identical to the proposed intensity for CPT code 33016, a relatively less intense service to perform, which would create a rank order anomaly within the family with respect to intensity.

Response: We appreciate the additional information from the commenters highlighting the pediatric nature of the patient population for CPT code 33018, and the potential for a rank order anomaly within the family with respect to intensity at the proposed work valuation. We agree with the commenters that CPT code 33018 should have the highest intensity among the four codes in this family.

Therefore, we are finalizing a work RVU of 5.40 for CPT code 33018 based on the RUC-recommended incremental relationship between this code and CPT code 33016 (a difference of 1.00 RVUs), which we are applying to our proposed value for the latter code. This work RVU will result in CPT code 33018 having the highest intensity out of the four codes in the family, in recognition of the additional difficulty and complexity of its pediatric patient population. We considered finalizing the RUC-recommended work RVU of 6.00 for CPT code 33018, which is based on a crosswalk to the emergency tracheostomy procedure described by CPT code 31603. However, we continue to have reservations about the use of this code as a crosswalk, as we believe that CPT code 31603 is a clear outlier in work valuation. As we stated in the proposed rule, the recommended crosswalk to CPT code 31603 had the highest work RVU among all of the codes in the RUC database with similar work time values, with only one other code in this group (CPT code 31600, another emergency tracheostomy procedure) having a work RVU higher than 4.69. These two tracheostomy procedures have work RVUs more than a full standard deviation above any of the other codes in this group of 0-day global procedures, and we believe these two codes to be outliers due to the serious risk of patient mortality associated with their performance. We believe that it is more accurate to use the RUC-recommended incremental relationship between this code and CPT code 33016 and finalize a work RVU of 5.40 for CPT code 33018, which recognizes the increased intensity of the procedure without crosswalking it to an outlier code with much greater risk of patient mortality.

Comment: Several commenters disagreed with the CMS proposed work RVU of 4.29 for CPT code 33019 and stated that CMS should instead finalize the RUC-recommended work RVU of 5.00. Commenters stated that the proposed work RVU for CPT code 33019 would create a rank order anomaly with respect to CPT code 33016. Commenters stated that although both procedures have distinct attributes, they both involve an identical amount of physician work.

Response: We disagree with the commenters that CPT codes 33016 and 33019 involve the identical amount of work. The survey respondents clearly did not believe that these two codes shared the same amount of work, as the surveys produced distinctly different work RVUs at the 25th percentile (5.00 against 4.29), the median (6.00 against 5.00), and the 75th percentile (7.85 against 5.44) for CPT codes 33016 and 33019, respectively. The survey respondents also recorded different intraservice times (30 minutes against 28 minutes) and total times (75 minutes against 84 minutes) for the two procedures. We believe that the survey data clearly demonstrates that CPT code 33019 should be valued at a lower work RVU than 33016, and we continue to believe that it was more accurate to propose a work RVU of 4.29 based on the survey 25th percentile.

After consideration of the public comments, we are finalizing the work RVUs for the codes in the Pericardiocentesis and Pericardial Drainage family as proposed, with the exception of CPT code 33018 where we are instead finalizing a work RVU of 5.40. We are also finalizing our proposal to have no direct PE inputs for these codes.

(10) Pericardiotomy (CPT Codes 33020 and 33025)

The RUC identified services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. CPT code 33020 (*Pericardiotomy for removal of clot or foreign body (primary procedure)*) and CPT code 33025 (*Creation of pericardial window or partial resection for drainage*) were surveyed for April 2018.

We disagreed with the RUC-recommended work RVU of 14.31 (25th percentile survey value) for CPT code 33020 and proposed a work RVU of 12.95. Our proposed work RVU is based on a crosswalk to CPT code 58700 (*Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)*), which has an identical work RVU of 12.95, identical 60 minutes intraservice time, and near identical total time values as CPT code 33020.

In our review of CPT code 33020, we noted that the RUC-recommended intraservice time is decreasing from 85 minutes to 60 minutes (29 percent reduction), and that the RUC-recommended total time is decreasing from 565 minutes to 321 minutes (43 percent reduction). However, the RUC-recommended work RVU is only decreasing from 14.95 to 14.31, which is a reduction of less than 5 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 33020, we believed that it would be more accurate to propose a work RVU of 12.95, based on a crosswalk to CPT code 58700 to account for these decreases in surveyed work times.

For CPT code 33025, the RUC recommended a work RVU of 13.20 (survey 25th percentile value). Although we disagreed with the RUC-recommended work RVU of 13.20, based on RUC survey results and the time resources involved in furnishing these two procedures we agreed that the relative difference in work RVUs between CPT codes 33020 and 33025 is equivalent to the RUC-recommended incremental difference of 1.11 less work RVUs. Therefore, we proposed a work RVU of 11.84 based on a reference to CPT code 34712 (*Transcatheter delivery of enhanced fixation devices(s) to the endograft (e.g., anchor, screw, tack) and all associated radiological supervision and interpretation),* which has a work RVU of 12.00, identical intraservice time of 60 minutes, and similar total time as CPT code 33025.

In reviewing CPT code 33025, we noted that the RUC-recommended intraservice time is decreasing from 66

minutes to 60 minutes (9 percent reduction), and that the RUC-recommended total time is decreasing from 410 minutes to 301 minutes (27 percent reduction). However, the RUC-recommended work RVU is only decreasing from 13.70 to 13.20, which is a reduction of less than 5 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 33025, we believed that it would be more accurate to propose a work RVU of 11.84, based on less the incremental difference of 1.11 work RVUs between CPT codes 33020 and 33025 and a crosswalk to CPT code 34712 to account for these decreases in surveyed work times.

We proposed the RUC-recommended direct PE inputs for all the codes in this family.

We received public comments on the proposed valuation of the codes in the Pericardiotomy family. The following is a summary of the comments we received and our responses.

Comment: A commenter noted that CMS misstated which code was identified via the RUC screen.

Response: We thank the commenter for bringing this to our attention. We have clarified how these codes came under review to reflect, as written in the RUC recommendations, that the RUC identified services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. The RUC recommended that these services be surveyed for April 2018.

Comment: Several commenters disagreed with the CMS-proposed work RVU of 12.95 for CPT code 33020 and stated that CMS should instead finalize the RUC-recommended work RVU of 14.31. Commenters stated the typical patient for CPT code 33020 is acutely ill and has typically encountered some type of trauma resulting in the need for intensive short-term care prior to and immediately following the procedure. A commenter further noted that CPT code 33020 requires more physician work and is more intense than the CMS cross walk, CPT code 58700, because during both the pre-service and intra-service time, continual monitoring of the patient's hemodynamics is required because of the risk of imminent cardiac tamponade.

Response: We appreciate the additional information from the commenters regarding the relative intensity of CPT codes 33020 and 58700. In light of this additional information, we agree with the commenters that CPT code 33020 has a higher intensity than CPT code 58700.

Comment: Several commenters stated that the incremental methodology used in valuing these services was flawed; commenters did not agree that it was appropriate to reduce the work RVU for CPT code 33025 from the value proposed by the RUC, relative to the RUC's recommended difference in work between this code and CPT code 33020. Commenters also noted that it is imperative to employ RUC survey data to value these codes, and that using an incremental approach in lieu of survey data, strong crosswalks, and input from the practitioners providing these services was unjustified.

Response: We appreciate the commenters' concerns regarding our use of time ratio methodologies in the code valuation process for establishing work RVUs. We have responded to concerns about our methodology earlier in this section of this final rule. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the ''Methodology for Establishing Work RVUs'' section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

After consideration of the public comments, we are not finalizing the proposed work RUVs for CPT codes 33020 and 33025, and instead are finalizing the RUC-recommended RVUs for the codes in the Pericardiotomy family. We are finalizing the direct PE inputs as proposed.

(11) Transcatheter Aortic Valve Replacement (TAVR) (CPT Codes 33361, 33362, 33363, 33364, 33365, and 33366)

In October 2016, the RUC's RAW reviewed codes that had been flagged in the period from October 2011 to April 2012, using 3 years of available Medicare claims data (2013, 2014 and preliminary 2015 data). The RUC workgroup concluded that the technology for these transcatheter aortic valve replacement (TAVR) services was evolving, as the typical site of service had shifted from being provided in academic centers to private centers, and the RUC recommended that CPT codes 33361–33366 be resurveyed for physician work and PE. These six codes were surveyed and reviewed at the April 2018 RUC meeting using a survey methodology that reflected the unique nature of these codes. CPT codes 33361–33366 are currently the only codes on the PFS where the -62 co-surgeon modifier is required 100 percent of the time.

We proposed the RUC-recommended work RVU for all six of the codes in this family. We proposed a work RVU of 22.47 for CPT code 33361 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach*), a work RVU of 24.54 for CPT code 33362 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach*), a work RVU of 25.47 for CPT code 33363 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach*), a work RVU of 25.97 for CPT code 33364 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach*), a work RVU of 26.59 for CPT code 33365 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)*), and a work RVU of 29.35 for CPT code 33366 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)*).

Although we have some concerns that the RUC-recommended work RVUs for these six codes do not match the decreases in surveyed work time, we recognize that the technology described by the TAVR procedures is in the process of being adopted by a much wider audience, and that there will be greater intensity on the part of the practitioner when this particular new technology is first being adopted. However, we intend to continue examining whether these services are appropriately valued, in light of the proposed national coverage determination proposing to use TAVR for the treatment of symptomatic aortic valve stenosis that we posted on March 26, 2019. We will also consider any further improvements to the valuation of these services, as their use becomes more commonplace, through future notice and comment rulemaking. The text of the proposed national coverage determination is available on the CMS website at *https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=293.*

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the

Transcatheter Aortic Valve Replacement family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they appreciate recognition of the complexities of this evolving technology by CMS and agreed with the proposal of the RUC-recommended work RVUS for all six of these codes.

Response: We appreciate the support for our proposals from the commenter.

Comment: Several commenters disagreed with the proposed work RVUs. Commenters disagreed with the proposed reduction in work RVUs for CPT codes 33361–33366 on the basis that the proposed values were too low and did not accurately reflect the actual work time and intensity required to perform all aspects of the procedures. Commenters stated that the amount of effort spent is not decreasing, and RVUs are shared equally between the surgeon and cardiologist. A commenter stated that the number of Medicare beneficiaries receiving TAVR was increasing rapidly due to FDA approval of an expanded TAVR indication in low surgical risk patients and a revised National Coverage Determination (NCD) published by CMS. This commenter stated that the RUC-recommended and CMS-proposed valuations do not include the time and PE costs associated with physicians' TAVR-related data requirements, and the commenter recommended delaying the adoption of the new work RVUs.

Response: We disagree with the commenters that the proposed work RVUs for CPT codes 33361–33366 were too low and that the implementation of these work RVUs should be delayed. The work surveys conducted by the RUC indicated that the typical intraservice work time decreased substantially for each code in the family since the last time of review in 2012. For example, CPT code 33361 decreased from a previous intraservice work time of 135 minutes to a newly surveyed intraservice work time of 90 minutes. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. This was the rationale for the RUC's recommendation of decreased work RVUs for the six codes in the family, which we shared in proposing these valuations. We also do not agree that an increase in utilization for the TAVR codes would necessarily be sufficient rationale for delaying their implementation, as there are many other services experiencing a high rate of growth for which we have not proposed a delay in valuation.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Transcatheter Aortic Valve Replacement family as proposed.

(12) Aortic Graft Procedures (CPT Codes 33858, 33859, 33863, 33864, 33871, and 33866)

In 2017, CPT created a new add-on code, CPT code 33866 (*Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)*). For CY 2019, we finalized the RUC's recommended work RVU for this code as proposed, and indicated that we would consider any coding changes or RUC recommendations in future rulemaking (83 FR 59528). CPT revised the code set to develop distinct codes for ascending aortic repair for dissection and ascending aortic repair for other ascending aortic disease such as aneurysms and congenital anomalies, creating two new codes, as well as revaluating the two other codes in the family.

For CPT code 33858 (*Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic dissection*), we disagree with the RUC-recommended work RVU of 65.00, because the RUC is recommending an increase in work RVU that is not commensurate with a reduction in physician time, and because we do not believe that the RUC's recommendation that this service be increased to a value that would place it among the highest valued of all services of similar physician time is appropriate; we believe a comparison to other services of similar time indicates that the RUC's recommended increase overstates the work. Instead, we proposed to increase the work RVU to 63.40 based on a crosswalk to CPT code 61697 (*Surgery of complex intracranial aneurysm, intracranial approach; carotid circulation*).

For CPT code 33859 (*Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic disease other than dissection (e.g., aneurysm)*), we disagree with the RUC-recommended work RVU of 50.00, because we do not believe it adequately reflects the recommended decrease in physician time, and because we do not believe this service should be assigned a value that is among the highest of all 90-day global services with similar physician time values. Instead, we proposed a work RVU of 45.13 based on a crosswalk to CPT code 33468 (*Tricuspid valve repositioning and plication for Ebstein anomaly*), which is a code with an identical intraservice time and similar total time value.

For CPT code 33863 (*Ascending aorta graft, with cardiopulmonary bypass, with aortic root replacement using valved conduit and coronary reconstruction (e.g., Bentall)*), according to the RUC, the survey respondents underestimated the intraservice time of the procedure and the RUC recommended a work RVU of 59.00 based on the 75th percentile of survey responses for intraservice time. We believe the use of the survey 75th percentile value to be problematic, as the intraservice time values should generally reflect the survey median. We are requesting that this code be resurveyed to determine more accurate physician time values, and we proposed to maintain the current RVU of 58.79 for CY 2020.

For CPT code 33864 (*Ascending aorta graft, with cardiopulmonary bypass with valve suspension, with coronary reconstruction and valve-sparing aortic root remodeling (e.g., David Procedure, Yacoub procedure)*), we do not agree with the RUC-recommended work RVU of 63.00, because we believe this increase is not justified given that the intraservice time is not changing from its current value, and the physician total time value is decreasing. Therefore, we proposed to maintain the current work RVU of 60.08 for this service.

For CPT code 33871 (*Transverse aortic arch graft, with cardiopulmonary bypass, with profound hypothermia, total circulatory arrest and isolated cerebral perfusion with reimplantation of arch vessel(s) (e.g., island pedicle or individual arch vessel reimplantation)*), we disagree with the RUC's recommended work RVU of 65.75. While we agree that an increase in work RVU is justified, as discussed above, we believe that the use of the 75th percentile of physician intraservice work time is problematic, and believe such a significant increase in work RVU is not validated. Therefore, we proposed a less significant increase to 60.88 using the RUC-recommended difference in work value between CPT code 33859 and the code in question, CPT code 33871 (a difference of 15.75). As further support for this value, we note that it falls between CPT codes 33782 (*Aortic root translocation with ventricular septal defect and pulmonary stenosis*

repair (i.e., Nikaidoh procedure); without coronary ostium reimplantation), which has a work RVU of 60.08, and CPT code 43112 (*Total or near total esophagectomy, with thoracotomy; with pharyngogastrostomy or cervical esophagogastrostomy, with or without pyloroplasty (i.e., McKeown esophagectomy or tri-incisional esophagectomy)*), which has a work RVU of 62.00. Both of these bracketing reference codes have similar intraservice and total time values.

For CPT code 33866 (*Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)*), we proposed the RUC-recommended work RVU of 17.75.

For the direct PE inputs, we proposed to refine the clinical labor to align with the number of post-operative visits. Thus, we proposed to add 12 minutes of clinical labor time for ''Discharge day management'' for CPT codes 33859, 33863, 33864, and 33871, as each of these codes include a 99238 discharge visit within their global periods that should be reflected in the clinical labor inputs.

We received public comments on the proposed valuation of the codes in the Aortic Graft Procedures family. The following is a summary of the comments we received and our responses.

Comment: One commenter disagreed with our proposed value for CPT Code 33858, and stated that our proposal ignores that deleted CPT code 33860 is a more general code than CPT code 33858, as 33860 is both used for emergent procedures (*e.g.,* repairs for aortic dissection) and for planned procedures (*e.g.,* repair for aortic diseases other than dissection), whereas CPT code 33858 is only the portion of CPT code 33860's volume that is emergent. Therefore, the commenter suggested that we should not compare physician times for the two codes as they describe different intensities. This commenter stated that CMS inappropriately rejected the RUC recommendation and instead picked an arbitrary low-volume crosswalk, last reviewed almost 15 years ago, with a work RVU only 2.5 percent less than the RUC recommendation. Furthermore, the commenter stated that this selected crosswalk is not an appropriate comparator, as CPT code 33858 involves three critical care visits, whereas the crosswalk code 61697 does not include any critical care.

Response: As we explained in the CY 2020 PFS proposed rule (84 FR 40575), our determination that the RUC's value overstates the work was based on an analysis of all codes with 90-day global periods. Our use of a crosswalk based on physician time is consistent with longstanding valuation methodology. We note that crosswalk CPT code 61697 has an intraservice time value that is identical to that of CPT code 33858, and a total time value that is over 20 percent higher than that of CPT code 33858; thus, we believe that the critical care component is adequately reflected in this value. The vignettes for CPT code 33858 and our crosswalk code, CPT code 61697, both describe complicated procedures for acutely ill patients; both involve significant vascular structures and are performed on urgent or emergent bases. Our examination of time values indicated that the RUC's work RVU was somewhat overstated, and we continue to believe that CPT code 61697 provides an appropriate crosswalk.

Comment: For CPT Code 33859, a commenter questioned our statement that we did not believe that the RUC-recommended work RVU adequately reflects the recommended decrease in physician time, stating that the change in total time from 931 minutes to 778 minutes is in close proportion to the change in value from the current value of 59.46 for the deleted code to the RUC recommendation of 50.00. This commenter stated that our proposed value for CPT 33871 is also flawed as it is based on an increment to CPT 33859.

Response: We disagree that the RUC's recommended reduction in work RVU is closely proportionate to the decrease in time. We disagree that physician time ratios indicate that the RUC-recommended value is closely proportionate to the time decrease. We note that, while the commenter cites the total time ratio, the intraservice time ratio indicate that the RUC's recommended value is somewhat overstated. Our crosswalk code CPT code 33468 and CPT code 33859 both involve bypass procedures, and have similar time values; CPT code 33468 has more total time than CPT code 33859. We continue to believe, given the time values and intensity involved in the two procedures, that CPT code 33468 is a strong crosswalk. For CPT code 33871, we note that our reference code CPT code 43112 has almost the same intraservice time value and 196 more minutes of total time, and further validates our proposed work RVU.

Comment: For CPT codes 33863 and 33871, a commenter stated that our rationales, which in part included an assumption on our part that the physician intraservice times were overstated in that they are the 75th percentile survey values, neglected to acknowledge or account for the STS Database intra-service times for these codes, which in the commenter's view support the RUC's recommended intra-service times. The commenter suggested that our request that these services be resurveyed ignores the RUC's rationale regarding the STS database times.

Response: We note that we did not ignore the STS database time data, and our proposed values for CPT codes 33863 and 33871 rely on times from this database, and we are finalizing the time values as recommended for these codes. We primarily rely on survey data for time values, however we continue to remain interested in a range of data sources and how to integrate these data sources into our ratesetting process.

Comment: A commenter disagreed with our proposal to maintain the current work RVU for CPT code 33864, and stated that our proposed value for CPT code 33864 would not have appropriate relativity compared to our proposed value for CPT code 33863, and that the former service involves more difficult and intense work than the latter. The commenter stated that CPT code 33864 involves replacing the aortic root and ascending aorta, but unlike CPT code 33863, attempts to preserve the patient's own native aortic valve—a procedure far more complex and skill-intensive than aortic valve replacement reflected in CPT code 33863. The increment of the RUC recommendations between these two services is 4.00 RVUs, whereas the increment for the CMS-proposed values is only 1.29 RVUs, which is not sufficient to account for the difference in work between these two services.

Response: We agree that CPT code 33864 is a more intense procedure than CPT code 33863, which is why we proposed a higher intensity for this procedure. However, we do not agree with the commenters that this greater intensity justifies the RUC-recommended work increment of 4.00 work RVUs between the two procedures. We believe that if CPT code 33864 typically required a significant amount of additional work in comparison to CPT code 33863, that work would have been reflected in the surveyed work times for the two procedures. Instead, the surveyed work times are identical between the two procedures. Absent evidence of additional work time from the survey respondents, we continue to believe that the proposed work RVU and proposed intensity for CPT code 33864 accurately

capture the increased difficulty of the procedure in comparison to CPT code 33863.

Comment: One commenter stated that they agreed with the proposed direct PE clinical labor refinements for these codes.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing work RVUs of 63.40 for 33858, 45.13 for 33859, 58.79 for CPT code 33863, 60.08 for CPT code 33864, 60.88 for CPT code 33871, and the RUC-recommended work RVU of 17.75 for CPT code 33866 as proposed. We are also finalizing the direct PE inputs as proposed.

(13) Iliac Branched Endograft Placement (CPT Codes 34717 and 34718)

For CY 2018, the CPT Editorial Panel created a family of 20 new and revised codes that redefined coding for endovascular repair of the aorta and iliac arteries. The iliac branched endograft technology has become more mainstream over time, and two new CPT codes were created to capture the work of iliac artery endovascular repair with an iliac branched endograft. These two new codes were surveyed and reviewed for the January 2019 RUC meeting.

We proposed the RUC-recommended work RVU of 9.00 for CPT code 34717 (*Endovascular repair of iliac artery at the time of aorto-iliac artery endograft placement by deployment of an iliac branched endograft including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for rupture or other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer, traumatic disruption), unilateral*) and the RUC-recommended work RVU of 24.00 for CPT code 34718 (*Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral*).

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Iliac Branched Endograft Placement family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposal of the RUC-recommended work RVU for both codes in the family.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Iliac Branched Endograft Placement family as proposed.

(14) Exploration of Artery (CPT Codes 35701, 35703, and 35703)

CPT code 35701 (*Exploration not followed by surgical repair, artery; neck (e.g., carotid, subclavian)*) was identified via a screen for services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. In September 2018, the CPT Editorial Panel revised one code, added two new codes, and deleted three existing codes in the family to report major artery exploration procedures and to condense the code set due to low frequency.

We proposed the RUC-recommended work RVU for all three codes in the family. We proposed a work RVU of 7.50 for CPT code 35701, a work RVU of 7.12 for CPT code 35702 (*Exploration not followed by surgical repair, artery; upper extremity (e.g., axillary, brachial, radial, ulnar)*), and a work RVU of 7.50 for CPT code 35703 (*Exploration not followed by surgical repair, artery; lower extremity (e.g., common femoral, deep femoral, superficial femoral, popliteal, tibial, peroneal)*).

For the direct PE inputs, we proposed to refine the clinical labor, supplies, and equipment to match the number of office visits contained in the global periods of the codes under review. We proposed to refine the clinical labor time for the ''Post-operative visits (total time)'' (CA039) activity from 36 minutes to 27 minutes for CPT codes 35701 and 35702, and from 63 minutes to 27 minutes for CPT code 35703. Each of these CPT codes contains a single postoperative level 2 office visit (CPT code 99212) in its global period, and 27 minutes of clinical labor is the time associated with this office visit. We proposed to refine the equipment time for the exam table (EF023) to the same time of 27 minutes for each code to match the clinical labor time. Finally, we are also proposing to refine the quantity of the minimum multi-specialty visit pack (SA048) from 2 to 1 for CPT code 35703 to match the single postoperative visit in the code's global period. We believe that the additional direct PE inputs in the recommended materials were an accidental oversight due to revisions that took place at the RUC meeting following the approval of the PE inputs for these codes.

We received public comments on the proposed valuation of the codes in the Exploration of Artery family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposed work RVUs and thanked CMS for correcting the PE to reflect the number of office visits contained in the global period.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Exploration of Artery family as proposed.

(15) Intravascular Ultrasound (CPT Codes 37252 and 37253)

In the CY 2015 PFS proposed rule, a stakeholder requested that CMS establish non-facility PE RVUs for CPT codes 37250 and 37251. CMS sought comment regarding the setting and valuation of these services. The CPT Editorial Panel deleted CPT codes 37250 *((Ultrasound evaluation of blood vessel during diagnosis or treatment)* and 37251 *(Ultrasound evaluation of blood vessel during diagnosis or treatment)* and created new bundled codes 37252 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel*) and 37253 *(Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel)* to describe intravascular ultrasound (IVUS). CMS finalized the RUC recommended work RVUs for intravascular ultrasound.

When CPT codes 37252 and 37253 were reviewed at the January 2015 RUC meeting, they were assumed to be work neutral compared to predecessor codes

CPT codes 37250 and 37251, meaning they would not result in an overall increase in work spending, and that they would result in an overall savings of work RVUs that would be redistributed to the Medicare conversion factor. Services are considered work neutral if, despite changes in coding, the overall amount of work RVUs for a set of services is held constant from one year to the next.

The RUC determined that, between CY 2015 and CY 2016, the overall work spending for these services went up by 44 percent as compared to the predecessor codes, thus disrupting the projected work neutrality. Observed utilization also doubled. In April 2018, the RUC reviewed this code family and found that the utilization of these services was underestimated, considering that the newer bundled codes included radiological supervision and interpretation.

Consequently, the RUC recommended that these services be surveyed for October 2018. The RUC indicated that the specialty societies should research why there was such an increase in the utilization. Accordingly, the specialty society surveyed these add-on codes, and the survey results indicated the intraservice and total work times, along with the work RVU should remain the same despite the RUC's underestimation of utilization for these codes.

We disagreed with the RUC-recommended work RVU of 1.80 for CPT code 37252 and proposed a work RVU of 1.55 based on a crosswalk to CPT code 19084. CPT code 19084 is a recently reviewed code with 20 minutes of intraservice time and 25 minutes of total time. In reviewing CPT code 37252, we note, as mentioned above, that in CY 2015 the specialty society expected that bundling this service would achieve work neutrality, meaning that new coding would not result in an overall increase in work spending. However, since 2015, observed utilization for CPT code 37252 has greatly exceeded estimated utilization. Therefore, we proposed for CY 2020 work RVUs based on crosswalk codes that would have resulted in restored work neutrality for the intravascular ultrasound code family.

For CPT code 37253, we disagreed with the RUC-recommended work RVU of 1.44 and we proposed a work RVU of 1.19. Although we disagreed with the RUC-recommended work RVU, we note the relative difference in work between CPT codes 37252 and 37253 is an interval of 0.36 RVUs. Therefore, we proposed a work RVU of 1.19 for CPT code 37253, based on the recommended interval of 0.36 fewer RVUs than our proposed work RVU of 1.55 for CPT code 37252.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Intravascular Ultrasound family. The following is a summary of the comments we received and our responses.

Comment: A few commenters disagreed with our proposed values for these codes and urged us to accept the RUC-recommended values. One commenter stated the increased utilization for these codes may be for a host of reasons, some of which include increased complexity of interventions being performed in the arterial, venous, and aortic spaces. This commenter stated that a large proportion of the utilization of this service is by a few physicians, and if we reduce the RVUs as proposed, many physicians and patients may be affected. The commenter stated that an attempt to enforce work neutrality may result in harm to a large group of patients while only a small group of physicians are responsible, and recommended that this issue should be addressed at a local level. The commenter stated that if CMS has continuing concerns about overutilization or outliers for CPT codes 37252 and 37253, the Agency can use LCDs and the RAC process. Another commenter disagreed with use of an incremental methodology to value CPT code 37253, suggesting that it inaccurately treats all components of the physician time as having identical intensity.

Response: We are persuaded that reducing work RVUs that would have resulted in work neutrality for these codes may not be appropriate, and that valuation in this instance should be determined irrespective of utilization. Comments indicate that the increase in utilization for these services may have occurred for a variety of reasons including those related to potential inappropriate billing by some practitioners. We would not ordinarily expect volume for a revised code family to change exponentially between the old and revised code sets, however we are persuaded by commenters that this is more appropriately addressed in this instance through an analysis of claims to determine potentially inappropriate billing by some practitioners. In response to public comment, we are finalizing the RUC-recommended work RVUs of 1.80 for CPT Code 37252 and 1.44 for CPT code 37253.

After consideration of the public comments, we not finalizing our proposed work RVUs, and we are instead finalizing the RUC-recommended work RVUs for CPT Codes 37252 and 37253. We are also finalizing the direct PE inputs as proposed.

(16) Stab Phlebectomy of Varicose Veins (CPT Codes 37765 and 37766)

These services were identified in February 2008 via the High Volume Growth screen, for services with a total Medicare utilization of 1,000 or more that have increased by at least 100 percent from 2004 through 2006. The RUC subsequently recommended monitoring and reviewing changes in utilization over multiple years. In October 2017, the RUC recommended that this service be surveyed for April 2018. We proposed the RUC-recommended work RVUs of 4.80 for CPT code 37765 (*Stab phlebectomy of varicose veins, 1 extremity; 10–20 stab incisions*) and 6.00 for CPT code 37766 (*Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions*). We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Stab Phlebectomy of Varicose Veins family. The following is a summary of the comments we received and our responses.

Comment: Commenters stated that they supported our proposal of the RUC-recommended work RVU and direct PE inputs for both codes in the family.

Response: We appreciate the support for our proposals from the commenters.

Comment: A few commenters stated that our proposals for these codes will result in unreasonable reductions in payment.

Response: We continue to believe that the RUC's recommended decreases in work RVUs are proportionate to the decreases in surveyed work times for these services.

Comment: A commenter stated that the RUC-recommended physician survey times are inaccurate, and the commenter requested that we consider data collected by the American Vein and Lymphatic Society as additional physician work time data.

Response: We welcome the submission of any additional data or information that would allow us to consider these codes for further review at a future time.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs as proposed. We are also finalizing the direct PE inputs as proposed.

(17) Biopsy of Mouth Lesion (CPT Code 40808)

CPT code 40808 (*Biopsy, vestibule of mouth*) was identified via a screen for services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes.

We disagree with the RUC's recommended work RVU of 1.05 with a crosswalk to CPT code 11440 (*Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.5 cm or less*), as we believe this increase in work RVU is not commensurate with the RUC-recommended 5-minute reduction in intraservice time and a 10-minute reduction in total time. While we understand that the RUC considers the current time values for this service to be invalid estimations, we do not see compelling evidence that would indicate that an increase in work RVU that would be concurrent with a reduction in physician time is appropriate. Therefore, we proposed to maintain the current work RVU of 1.01, and note that implementing the current work RVU with the RUC-recommended revised physician time values would correct the negative IWPUT anomaly.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes. As we detailed when discussing this issue in the CY 2019 PFS final rule (83 FR 59463 through 59464), CPT code 40808 does not include the old clinical labor task ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'' on a prior version of the PE worksheet, nor does the code contain any clinical labor for the CA007 activity (''Review patient clinical extant information and questionnaire''). CPT code 40808 does not appear to be an instance where an old clinical labor task was split into two new clinical labor activities, and we continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code. We also note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished.

We are also proposing to refine the equipment time for the electrocautery-hyfrecator (EQ110) to conform to our established policies for non-highly technical equipment.

We received public comments on the proposed valuation of the codes in the Biopsy of Mouth Lesion family. The following is a summary of the comments we received and our responses.

Comment: One commenter disagreed with our rationale, stating that it ignores that the RUC reviewed and accepted compelling evidence that the original valuation was based on flawed methodology when it was reviewed in 1995, resulting in a negative IWPUT. The value of the service was maintained without taking into consideration the times newly assigned to the service in 1995. That resulted in the physician time and work value having a distorted relationship. The commenter stated that, contrary to the assertion made in the proposed rule, this compelling evidence makes a strong case that the work was formerly misvalued. The commenter asserted that if a work value was assigned by CMS in 1995 without CMS appropriately being informed by physician time data, then the work value assigned prior to the RUC's 2018 analysis used an inappropriate methodology. The commenter also stated that the IWPUT derived from the RUC recommendation is only 0.0194, while the IWPUT of CMS' alternate proposal, 0.0153, would be less than twice the intensity assigned to pre-service scrub/dress/wait time and inappropriately low for the intra-service time of this service or for that matter, the clear majority of all services in the Medicare PFS.

Response: We are persuaded by the comments regarding the problematic nature of using the source physician time, as well as the derived intensity, to revalue this code, and agree with the commenter that the RUC-recommended work RVU of 1.05 for CPT code 40808 is appropriate.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes. Commenters stated that 1 minute was required to order the pathology and complete the request form, including patient history, location, differential diagnosis, and staff processing time. Another commenter stated that they supported the proposal to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes, but noted that an additional minute is required for the CA014 activity to order the specimen for pathology to review.

Response: We continue to disagree with the commenters that 1 minute should be assigned for the CA014 clinical labor activity in CPT code 40808. As we stated in the proposed rule, CPT code 40808 does not include the old clinical labor task ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'' on a prior version of the PE worksheet, nor does the code contain any clinical labor for the CA007 activity or appear to be an instance where an old clinical labor task was split into two new clinical labor activities. We continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 activity code, and commenters did not supply any rationale as to why this would not be the case. We also note once again that there is no effect on the total clinical labor direct costs from these refinements, since the same 3 minutes of clinical labor time is still being furnished.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 1.05 for CPT code 40808 rather than our proposed value of 1.01. We are also finalizing the direct PE inputs as proposed.

(18) Transanal Hemorrhoidal Dearterialization (CPT Codes 46945, 46946, and 46948)

We proposed the RUC-recommended work RVU for all three codes in the family. We proposed a work RVU of 3.69 for CPT code 46945 (*Hemorrhoidectomy, internal, by ligation other than rubber band; single hemorrhoid column/group, without imaging guidance*), a work RVU of 4.50 for CPT code 46946 (*2 or more hemorrhoid columns/groups, without imaging guidance*), and a work RVU of 5.57 for CPT code 46948 (*Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy when performed*).

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Transanal Hemorrhoidal Dearterialization family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposal of the RUC-recommended work RVU for both codes in the family.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Transanal Hemorrhoidal Dearterialization family as proposed.

(19) Preperitoneal Pelvic Packing (CPT Codes 49013 and 49014)

In May 2018, the CPT Editorial Panel approved the addition of two codes for preperitoneal pelvic packing, removal and/or repacking for hemorrhage associated with pelvic trauma. These new codes were surveyed and reviewed for the October 2018 RUC meeting.

We disagree with the RUC-recommended work RVU of 8.35 for CPT code 49013 (*Preperitoneal pelvic packing for hemorrhage associated with pelvic trauma, including local exploration*) and proposed a work RVU of 7.55 based on a crosswalk to CPT code 52345 (*Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (e.g., balloon dilation, laser, electrocautery, and incision)*). We are also proposing to reduce the immediate postservice work time from 60 minutes to 45 minutes, which results in a total work time of 140 minutes for this procedure. We believe that the survey respondents overstated the immediate postservice work time that would typically be required to perform CPT code 49013, which we investigated by comparing this new service against the existing 0-day global codes on the PFS. We found that among the roughly 1100 codes with 0-day global periods, only 21 codes had an immediate postservice work time of 60 minutes or longer. The 21 codes that fell into this category had significantly higher intraservice work times than CPT code 49013, with an average intraservice work time of 111 minutes as compared to the 45 minutes of intraservice work time in CPT code 49013. Generally speaking, it is extremely rare for a service to have more immediate postservice work time than intraservice work time, and in fact only 28 out of the roughly 1100 codes with 0-day global periods had more immediate postservice work time than intraservice work time. While we agree that each service on the PFS is its own unique entity, these comparisons to other 0-day global codes suggest that the survey respondents overestimated the amount of immediate postservice work time that would typically be associated with CPT code 49013.

As a result, we believe that it would be more accurate to reduce the immediate postservice work time to 45 minutes and to propose a work RVU of 7.55 based on a crosswalk to CPT code 52345. This crosswalk code shares an intraservice work time of 45 minutes and a similar total time of 135 minutes after taking into account the reduced immediate postservice work time that we proposed for CPT code 49013. We searched the RUC database for 0-day global procedures with 45 minutes of intraservice work time, and at the recommended work RVU of 8.35, CPT code 49013 would establish a new maximum value, higher than all of the 79 other codes that fall into this category. We recognize that CPT code 49013 describes a preperitoneal pelvic packing service associated with pelvic trauma, and that this is a difficult and intensive procedure that rightly has a higher work RVU than many of these other 0-day global codes. However, we believe that it better maintains relativity to propose a crosswalk to CPT code 52345 at a work RVU of 7.55, which would still assign this code the second-highest work RVU among all 0 day global codes with 45 minutes of intraservice work time, as opposed to proposing the survey median work RVU of 8.35 at a rate higher than anything in the current RUC database.

We disagree with the RUC-recommended work RVU of 6.73 for CPT code 49014 (*Re-exploration of pelvic wound with removal of preperitoneal pelvic packing including repacking, when performed*) and proposed a work RVU of 5.70 based on the 25th percentile survey value. We believe that the survey 25th percentile work RVU more accurately describes the work of re-exploring this type of pelvic wound, and by proposing the survey 25th percentile we are maintaining the general increment in RVUs between the two codes in the family (a difference of 1.62 RVUs as recommended by the RUC as compared to 1.85 RVUs as proposed here). We are supporting this valuation with a reference to CPT code 39401 (*Mediastinoscopy; includes biopsy(ies) of mediastinal mass (e.g., lymphoma), when performed*), a recently reviewed code from CY 2015 which shares the same intraservice time of 45 minutes, a slightly higher total time of 142 minutes and a lower work RVU of 5.44.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Preperitoneal Pelvic Packing family. The following is a summary of the comments we received and our responses.

Comment: Many commenters disagreed with the CMS proposed work RVU of 7.55 for CPT code 49013 and stated that CMS should instead finalize the RUC-recommended work RVU of 8.35. Commenters stated that the typical patient for CPT code 49013 is a critically injured emergent patient and that the procedure typically is performed as expeditiously as possible to avoid a hemorrhagic death of the patient. Commenters stated that CPT code 52345 is an elective outpatient operation, not an emergent procedure, and therefore, it was inarguable that the intensity of work for CPT code 49013 is considerably greater despite the two procedures sharing the same intraservice work time. Commenters disagreed with the CMS comparison of the postoperative time for code 49013 to other 0-day global procedures, stating that this took place without consideration of the type of work that is required for this code. Commenters stated that there are less than 800 0-day global codes that have been reviewed by the RUC, and that almost 240 of those procedures are endoscopy services performed electively under moderate sedation, while another 125 of those procedures include simple injections, biopsies, casting/strapping services, trimming nails, simple repair of wounds, and osteopathic and chiropractic services. Commenters stated that it was inappropriate and incorrect to equate code 49013 to these types of 0-day global codes for purposes of reviewing postoperative time.

Commenters also disagreed with the CMS-proposed immediate postservice work time of 45 minutes and stated that CMS should instead finalize the RUC-recommended work time of 60 minutes. Commenters stated that the immediate postservice work time of CPT code 49013 includes all postoperative care until midnight on the day of the procedure, a period where the patient will still be unstable and critical and their hemodynamic status will need to be monitored very closely. Commenters stated that due to the rare emergency nature of the procedure 60 minutes of postoperative time in the operating room, recovery unit, and intensive care unit on the day of this procedure would be typical. Commenters also pointed to the survey data for CPT code 49013, in which over 65 percent of all survey respondents indicated 50 minutes or more of postoperative time and of the 28 respondents with recent (12 month) experience, 60 percent indicated 60 minutes or more of postoperative work time. Commenters stated that there was no evidence to the contrary that these experienced providers overestimated the time they spend postoperatively on the day of the procedure.

Response: We appreciate the additional feedback from the commenters regarding the typical patients undergoing CPT code 49013 and the nature of the postoperative care that they will typically receive. Based on the additional information supplied by the commenters, we are not finalizing our refinements to the work RVU or postoperative work time for this code.

Comment: Many commenters disagreed with the CMS proposed work RVU of 5.70 for CPT code 49014 and stated that CMS should instead finalize the RUC-recommended work RVU of 6.73. Commenters stated that the typical patient undergoing CPT code 49014 will likely still be critically ill and unstable having survived significant pelvic trauma 24 to 48 hours prior to the procedure. Commenters disagreed with the CMS comparison to CPT code 39401, which describes a diagnostic biopsy procedure that is typically performed as an outpatient procedure on a stable patient. Commenters stated that the intensity of removing the preperitoneal pelvic pads one by one while ensuring the patient remains hemodynamically stable, as described by CPT code 49014, is much greater than taking mediastinal biopsies as described by CPT code 39401. One commenter provided a table that outlined several recently reviewed 0-day global codes with similar intraoperative time and intensity as code 49014, and stated that these codes supported the RUC-recommended work RVU of 6.73.

Response: We appreciate the additional feedback from the commenters regarding the typical patients undergoing CPT code 49014. Based on the additional information supplied by the commenters, we are not finalizing our refinement to the work RVU for this code.

After consideration of the public comments, we are not finalizing our proposed refinements to the work RVUs or the work times for the codes in the Preperitoneal Pelvic Packing family. We are instead finalizing the RUC-recommended work RVU of 8.35 for CPT code 49013 and the RUC-recommended work RVU of 6.73 for CPT code 49014. We are also finalizing the RUC-recommended immediate postservice work time of 60 minutes for CPT code 49013. We are finalizing the RUC-recommended direct PE inputs for both codes in the family as proposed.

(20) Cystourethroscopy Insertion Transprostatic Implant (CPT Codes 52441 and 52442)

In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the AMA/Specialty Society RVS Update Committee. This service was reviewed at the October 2018 RAW meeting, and the RAW indicated that the utilization is increasing and questioned the time required to perform these services. These two codes were surveyed and reviewed for the January 2019 RUC meeting.

We disagree with the RUC-recommended work RVU of 4.50 (current value) for CPT code 52441 (*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant*) and proposed a work RVU of 4.00. This proposed work RVU is based on a crosswalk from recently reviewed CPT code 58562 (*Hysterscopy, surgical; with removal of impacted foreign body*), which has a work RVU of 4.00, and an identical 25 minutes of intraservice time as CPT code 52441.

We disagree with the RUC-recommended work RVU of 1.20 (current value) for CPT code 52442 (*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)*) and proposed a work RVU of 1.01. This proposed work RVU is based on a crosswalk from CPT code 36218 (*Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)*), which has a work RVU of 1.01, and an identical 15 minutes of intraservice time as CPT code 52442.

The RUC survey showed a reduction in time, and the work should reflect these changes.

We proposed the RUC-recommended direct PE inputs for all codes in the family without refinement.

We received public comments on the proposed valuation of the codes in the Cystourethroscopy Insertion Transprostatic Implant family. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the CMS proposed work RVU of 4.00 for CPT code 52441 and stated that CMS should instead finalize the RUC-recommended work RVU of 4.50. One commenter stated the RUC recommendation for code 52441 was understated, but would support the RUC recommendation at this time. Commenters stated that the CMS proposal completely disregards all factors that go into the work value apart from time and, if finalized, would create a rank order anomaly relative to other urological procedures. Commenters stated that although the intraservice time for CPT code 52441 has decreased from 30 minutes to 25 minutes, the physician work for the procedure is now more intense.

Response: We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. We continue to believe that recently reviewed CPT code 58562 with an identical 25 minutes of intraservice time is a strong crosswalk and a work RVU of 4.00 is a more accurate valuation for code 52441.

Comment: A few commenters disagreed with our comparison of code 52441 to code 58562 because they are unrelated procedures, and also stated that removal of an intrauterine foreign body is not the same procedure as placement of a transprostatic implant and does not require as much skill and decision.

Response: We disagree with the commenters that CPT code 58562 is not an appropriate crosswalk code on the grounds that it is an unrelated procedure. We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters disagreed with the CMS proposed work RVU of 1.01 for CPT code 52442 and stated that CMS should instead finalize the RUC-recommended work RVU of 1.20. One commenter stated the RUC recommendation for code 52442 was understated and suggested the work RVU should be increase to 2.09 using a

crosswalk to code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)*). Commenters stated that although the intraservice time for CPT code 52442 has decreased from 25 minutes to 15 minutes, the physician work for the procedure is now more intense. Commenters stated that the CMS proposal for code 52442 completely disregards all factors that go into the work value apart from time and, if finalized, would create a rank order anomaly relative to other urological procedures.

Response: We disagree that CPT code 36227 is a better comparator to code 52442. Code 36227 is significantly more intense than the reviewed code 52442 because it involves catheter insertion into the external carotid artery, and we do not believe that it would be an appropriate comparison code. We agree with the commenters that intensity has increased for code 52442. This is the reason why we crosswalked the work RVU of code 36218 to code 52442. Code 36218 has the same intraservice time of 15 minutes and a higher intensity than code 52442. According to the RUC database, the intensity of work per unit of time (IWPUT) is greater for code 36218 than for code 52442. We continue to believe that CPT code 36218 with an identical 15 minutes of intraservice time is a strong crosswalk and a work RVU of 1.01 is a more accurate valuation for code 52442.

After consideration of the public comments, we are finalizing the work RVUs and the direct PE inputs for the codes in the Cystourethroscopy Insertion Transprostatic Implant family of codes (CPT codes 52441 and 52442) as proposed.

(21) Orchiopexy (CPT Code 54640)

The CPT Editorial Panel revised existing CPT code 54640 to describe an additional approach for orchiopexy (scrotal) and to clearly indicate that hernia repair is separately reportable. This code was surveyed and reviewed for the January 2019 RUC meeting.

We proposed to maintain the current work RVU of 7.73 as recommended by the RUC. We proposed the RUC-recommended direct PE inputs for CPT code 54640 without refinement.

We received public comments on the proposed valuation of CPT code 54640 for Orchiopexy. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of our proposal of the RUC-recommended work RVUs.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs and direct PE inputs for Orchiopexy (CPT code 54640).

(22) Radiofrequency Neurotomy Sacroiliac Joint (CPT Codes 64451, 64625)

In September 2018, the CPT Editorial Panel created two new codes to describe injection and radiofrequency ablation of the sacroiliac joint with image guidance for somatic nerve procedures. We proposed the RUC-recommended work RVU of 1.52 for CPT code 64451 (*Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)*) and the RUC-recommended work RVU of 3.39 for CPT code 64625 (*Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)*).

For the direct PE inputs, we proposed to refine the quantity of the ''needle, 18–26g 1.5–3.5in, spinal'' (SC028) supply from 3 to 1 for CPT code 64451. There are no spinal needles in use in the reference code associated with CPT code 64451, and there was no explanation in the recommended materials explaining why three such needles would be typical for this procedure. We agree that the service being performed in CPT code 64451 would require a spinal needle, but we do not believe that the use of three such needles would be typical.

We proposed to refine the quantity of the ''cannula (radiofrequency denervation) (SMK–C10)'' (SD011) supply from 4 to 2 for CPT code 64625. We do not believe that the use of 4 of these cannula would be typical for the procedure, as the reference code currently used for destruction by neurolytic agent contains only a single cannula. We believe that the nerves would typically be ablated one at a time using this cannula, as opposed to ablating four of them simultaneously as suggested in the recommended direct PE inputs. We also searched in the RUC database for other CPT codes that made use of the SD011 supply, and out of the seven codes that currently use this item, none of them include more than 2 cannula. As a result, we proposed to refine the supply quantity to 2 cannula to match the highest amount contained in an existing code on the PFS. We are also refining the equipment time for the ''radiofrequency kit for destruction by neurolytic agent'' (EQ354) equipment from 164 minutes to 82 minutes. The RUC's equipment time recommendation was predicated on the use of 4 of the SD011 supplies for 41 minutes apiece, and we are refining the equipment time to reflect our supply refinement to 2 cannula. It was unclear in the recommended materials as to whether the radiofrequency kit equipment was in use simultaneously or sequentially along with the cannula supplies, and therefore, we are soliciting comments on the typical use of this equipment.

Finally, we proposed to refine the equipment time for the technologist PACS workstation (ED050) equipment to match our standard equipment time formulas, which results in an increase of 5 minutes of equipment time for both codes.

We received public comments on the proposed valuation of the codes in the Radiofrequency Neurotomy Sacroiliac Joint family. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the CMS proposal to refine the quantity of the ''needle, 18–26g 1.5–3.5in, spinal'' (SC028) supply from 3 to 1 for CPT code 64451. Commenters stated that this code describes four separate injections of three sacral levels, and that four separate needles are required to inject the dorsal rami of L5 and the lateral branches of S1, S2 and S3. Commenters clarified that although the original RUC recommendation indicated that only 3 needles are needed for CPT code 64451, this was an error and the recommendation should in fact be 4 needles. Commenters stated that standard practice is to place the four needles, then simultaneously inject, and that if one needle were to be used there would be additional time required to account for the sequential fashion of the injections.

Response: We appreciate the additional information provided by the commenters regarding the SC028 spinal needle supply, especially the clarification that the use of four needles would be typical for the procedure. This was particularly helpful in resolving the discrepancy between the original recommendation of three needles and the four injections taking place. Although we continue to have reservations as to whether four simultaneous injections would be typical for this procedure, we are finalizing a supply quantity of 4 spinal needles for CPT code 64451 as recommended by the commenters.

Comment: Several commenters disagreed with the CMS proposal to refine the quantity of the ''cannula (radiofrequency denervation) (SMK–C10)'' (SD011) supply from 4 to 2 for CPT code 64625. Commenters stated that, in a similar fashion to CPT code 64451, the radiofrequency ablation of the nerves innervating the sacroiliac joint in CPT code 64625 requires four cannulas for simultaneous ablation of the four nerves. Commenters stated that these cannula are placed and then guided simultaneously to allow for fewer fluoroscopic images and a safer total radiation dose for the patient and staff. Commenters also noted that the comparison codes referenced in the proposed rule involved an ablation of a single nerve, and that while this was an excellent base comparison, CPT code 64625 reflects four times that work. Commenters requested that CMS finalize the RUC-recommended supply quantity of 4 cannulas.

Response: We appreciate the additional information provided by the commenters regarding the SD011 cannula supply, especially the reminder that the other comparison codes containing a cannula supply involved the ablation of a single nerve instead of four nerves. As we stated with regard to the spinal needle supple for CPT code 64451, we continue to have reservations as to whether four simultaneous ablations would be typical for this procedure; however, we are finalizing a supply quantity of 4 cannula for CPT code 64625 as recommended by the commenters.

Comment: Several commenters disagreed with the CMS proposal to refine the equipment time for the ''radiofrequency kit for destruction by neurolytic agent'' (EQ354) equipment from 164 minutes to 82 minutes. Commenters stated that four kits are used for 41 minutes each totaling 164 minutes, as the 41 minutes (times 4) occurs simultaneously. Commenters stated again that four cannulas and four kits are needed for the simultaneous ablation of four nerves.

Response: Since we did not finalize our proposal to refine the quantity of the SD011 cannula supply from 4 to 2 for CPT code 64625, we are also not finalizing our refinement to the EQ354 equipment time. We will instead finalize the RUC-recommended equipment time of 164 minutes for the radiofrequency kit.

Comment: Several commenters stated that the proposed reduction in RVUs for knee genicular nerve ablation and sacroiliac joint ablation will effectively reduce access for Medicare beneficiaries to reasonable and sensible treatments for chronic knee and low back pain respectively. The commenters detailed the clinical benefits of these procedures and requested that the proposed reduction in RVUs for knee and sacroiliac joint ablation not be enacted, as the commenters stated that doing so would jeopardize their ability to responsibly treat a large number of patients.

Response: We appreciate the feedback from the commenters detailing their experience with these procedures and their clinical importance to Medicare beneficiaries. We agree that it is extremely important to ensure reasonable and fair payment for each service in order to maintain access to care. In the particular case of the codes in the Radiofrequency Neurotomy Sacroiliac Joint family, we agreed with the RUC recommendations for work valuation and proposed the recommended work RVUs without refinement. We believe that this valuation will ensure that providers are properly compensated for these services.

After consideration of the public comments, we are finalizing the work RVUs for the codes in the Radiofrequency Neurotomy Sacroiliac Joint family as proposed. We are finalizing the RUC-recommended direct PE inputs for both codes in the family, with the exception of a refinement from 3 to 4 spinal needles (SC028) for CPT code 64451 and the proposed equipment time refinements for the technologist PACS workstation (ED050) equipment to match our standard equipment time formulas.

(23) Lumbar Puncture (CPT Codes 62270, 62328, 62272, and 62329)

In October 2017, these services were identified as being performed by a different specialty than the specialty that originally surveyed this service. In January 2018, the RUC recommended that these services be referred to CPT to bundle image guidance. At the September 2018 CPT Editorial Panel meeting, the Panel created two new codes to bundle diagnostic and therapeutic lumbar puncture with fluoroscopic or CT image guidance and revised the existing diagnostic and therapeutic lumbar puncture codes so they would only be reported without fluoroscopic or CT guidance.

For CPT code 62270 (*Spinal puncture, lumbar, diagnostic*), we disagree with the RUC-recommended work RVU of 1.44 and we proposed a work RVU of 1.22 based on a crosswalk to CPT code 40490 (*Biopsy of lip*). CPT code 40490 has the same intraservice time of 15 minutes and 2 additional minutes of total time. In reviewing CPT code 62270, we noted that the recommended intraservice time is decreasing from 20 minutes to 15 minutes (25 percent reduction), and the recommended total time is decreasing from 40 minutes to 32 minutes (20 percent reduction); however, the RUC-recommended work RVU is increasing from 1.37 to 1.44, which is an increase of just over 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 62270, we believed that it was more accurate to propose a work RVU of 1.22 based on a crosswalk to CPT code 40490 to account for these decreases in the surveyed work time.

For CPT code 62328 (*Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance*), we disagree with the RUC-recommended work RVU of 1.95 and we proposed a work RVU of 1.73. Although we disagree with the RUC-recommended work RVU, we note that the relative difference in work between CPT codes 62270 and 62328 is equivalent to an interval of 0.51 RVUs. Therefore, we proposed a work RVU of 1.73 for CPT code 62328, based on the recommended interval of 0.51 additional RVUs above our proposed work RVU of 1.22 for CPT code 62270.

For CPT code 62272 (*Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter*), we disagree with the RUC-recommended work RVU of 1.80 and we proposed a work RVU of 1.58. Although we disagree with the RUC-recommended work RVU, we note that the relative difference in work between CPT codes 62270 and 62328 is equivalent to the RUC-recommended interval of 0.36 RVUs. Therefore, we proposed a work RVU of 1.58 for CPT code 62272, based on the recommended interval of 0.36 additional RVUs above our proposed work RVU of 1.22 for CPT code 62270.

For CPT code 62329 (*Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance*), we disagree with the RUC-recommended work RVU of 2.25 and we proposed a work RVU of 2.03. Although we disagree with the RUC-recommended work RVU, we note that the relative difference in work between CPT codes 62270 and 62329 is equivalent to the recommended interval of 0.81 RVUs. Therefore, we proposed a

work RVU of 2.03 for CPT code 62329, based on the recommended interval of 0.81 additional RVUs above our proposed work RVU of 1.22 for CPT code 62270.

We proposed the RUC-recommended direct PE inputs for all four codes in the family without refinement.

We received public comments on the proposed valuation of the codes in the Lumbar Puncture family. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the CMS-proposed work RVU of 1.22 for CPT code 62270 and stated that CMS should instead finalize the RUC-recommended work RVU of 1.44. Commenters stated that the proposed crosswalk to CPT code 40490 was inappropriate and was chosen based only on a time comparison without consideration to the intensity of the work. Commenters stated that CPT code 62270 had a very different and more intensive patient population that the proposed crosswalk to CPT code 40490, with the crosswalk code typically performed in a physician office as an elective procedure while code CPT code 62270 is typically performed on seriously ill patients in the emergency room or inpatient hospital setting. Commenters stated that CPT code 62270 is a more intense and complex procedure because it involves insertion of a needle to at least a depth of 6–7 cm in the average sized patient while navigating around spine anatomy such as subcutaneous soft tissues, paraspinal muscles, spinous process, interspinous ligament, transverse process, epidural space and dura to access the cerebrospinal space. Commenters also stated that these two procedures were not clinically similar, as CPT code 40490 is a superficial biopsy of a visible lesion whereas CPT code 62270 requires the physician to guide a needle from the skin, through the soft tissues, between the posterior elements of the lumbar spine, and into the thecal sac within the spinal canal in a patient that is presenting with neurologic symptoms necessitating an emergent procedure.

Response: We disagree with the commenters that CPT code 40490 was an inappropriate choice to use as a crosswalk for work valuation, and we did not choose this code based only on a time comparison without respect to intensity. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work. We clarify again that we do not treat all components of physician time as having identical intensity. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

In more general terms, we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. We also note that the RUC-recommended crosswalk code used to determine the recommended work RVU of 1.44, CPT code 12004, is itself not clinically similar to CPT code 62270. While both procedures include an initial injection, they are otherwise clinically distinct from one another, with CPT code 12004 describing repair of superficial wounds while CPT code 62270 describes a spinal puncture for the purpose of obtaining cerebrospinal fluid samples. We do not understand the critique of CPT code 40490 as a clinically dissimilar code on the part of the commenters when the recommended work RVU of 1.44 is also based on a clinically dissimilar code.

For the specific case of CPT code 40490, while it is true that this is not an emergent procedure, the service nonetheless requires tissue excision and carries a substantial risk of serious bleeding from the patient. To the extent that commenters stated that CPT code 62270 is a more intense procedure than CPT code 40490, we agree with the commenters, which is why we proposed a higher intensity for CPT code 62270 in the proposed rule. We also note that CPT code 40490 was not the only crosswalk code that we could have chosen for work valuation. We also considered CPT code 12013 (*Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm*), an MPC code with the same 15 minutes of intraservice time, 27 minutes of total time, and the same work RVU of 1.22. If the commenters have reason to believe that wound repair procedures such as CPT code 12004 are more appropriate choices as crosswalks on clinical grounds, we emphasize that we also could have chosen CPT code 12013 (another wound repair procedure) for our crosswalk and still derived the same work RVU of 1.22.

Comment: Several commenters disagreed with the CMS-proposed work RVUs for CPT codes 62328, 62272, and 62329. Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for these procedures. Commenters stated that the incremental methodology used in valuing these services was flawed; commenters did not agree that it was appropriate to reduce the work RVU for CPT code 62270 from the value proposed by the RUC, while also recalibrating the work RVUs for CPT codes 62328, 62272, and 62329 relative to the RUC's recommended difference in work between these code and CPT code 62270. Commenters stated that patients for CPT code 62328 have typically failed a bedside lumbar puncture or have prior history of spine surgery that requires imaging to facilitate access into the cerebrospinal fluid space, and therefore, calculating a step-up in value from CPT code 62270 does not accurately capture the work differences. Commenters stated that it is imperative to employ RUC survey data to value these codes, and that using an incremental approach in lieu of survey data, strong crosswalks, and input from the practitioners providing these services was unjustified.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the consideration of an incremental difference between codes for the work component would be an inaccurate methodology to use for identifying the work resources in time and intensity involved in furnishing the service. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: Several commenters stated the crosswalk or methodology used in the original valuation of CPT code 62272 is unknown and not resource-based, and therefore, it was invalid for CMS to compare the current time and work to the surveyed time and work. Commenters stated that referencing physician times and derived intensities created almost 30 years ago under the Harvard study as a method to critique RUC recommendations was not appropriate.

Response: We believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily-obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). We also note that for the specific case of CPT code 62272, our proposed work RVU of 1.58 was based on the use of an incremental methodology and was unrelated to the existing work time values.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Lumbar Puncture family as proposed.

(24) Electronic Analysis of Implanted Pump (CPT Codes 62367, 62368, 62369, and 62370)

CPT code 62368 (*Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming*) was identified by the RUC on a list of services which were originally surveyed by one specialty but are now typically performed by a different specialty. It was reviewed along with three other codes in the family for PE only at the April 2018 RUC meeting. The RUC did not recommend work RVUs for these codes and we did not propose to change the current work RVUs.

For the direct PE inputs, we proposed to remove the minimum multi-specialty visit pack (SA048) from CPT code 62370 as a duplicative supply due to the fact that this code is typically billed with an E/M or other evaluation service.

We received public comments on the proposed valuation of the codes in the Electronic Analysis of Implanted Pump family. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to remove the minimum multi-specialty visit pack (SA048) from CPT code 62370 as a duplicative supply.

Response: We appreciate the support for our proposal from the commenters.

Comment: Several commenters disagreed with the proposed reduction in the nonfacility PE RVUs for the Electronic Analysis of Implanted Pump family of codes. The commenters detailed the use of implantable infusion pumps for the treatment of spasticity and chronic intractable pain and stated that they had concerns that the proposed physician payment reductions could threaten access to this important alternative therapy. The commenters stated that CMS provided commentary in the proposed rule about removing the minimum multi-specialty visit pack (SA048) from CPT code 62370 but there was no rationale given for a reduction of this magnitude applying across the entire family of codes. The commenters stated that they did not believe that a reduction in clinical labor time for these services was warranted, and restated that reducing the clinical labor time and cutting payment to physician offices for these codes, without a basis for doing so, was inappropriate.

Response: We clarify for the commenters that we proposed to remove the minimum multi-specialty visit pack (SA048) only from CPT code 62370, as a duplicative supply due to the fact that this code is typically billed with an E/M or other evaluation service. We did not propose to remove the SA048 visit pack from CPT code 62369 as this code is not typically billed with an E/M service. Aside from this singular refinement, we proposed the RUC-recommended direct PE inputs without refinement for the four codes in the family. We agree with the RUC that the typical clinical labor time required to perform these services has decreased significantly since they were last reviewed in 2011, particularly in light of the fact that three of the four codes are typically billed with a same day E/M service.

Comment: A commenter stated that the RUC and CMS applied significant reductions to clinical labor inputs for CPT codes 62367 and 62368 because these services are billed more than 50 percent of the time with E/M office visit services. The commenter stated that while this may be the case, the underlying rationale—that clinical staff times are redundant—does not apply to these services. The commenter stated that neuromodulation physician offices provide these services to patients every day, and the time spent by clinical staff is not duplicative and is not captured by any accompanying E/M codes.

Response: In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit, and we believe that the clinical labor tasks are similarly duplicative. For example, we do not believe that clinical labor tasks such as ''Greet patient, provide gowning, ensure appropriate medical records are available'' (CA009) and ''Prepare room, equipment and supplies'' (CA013) would typically be performed in CPT code 62367 given that clinical labor time is already allocated for these identical tasks in the E/M codes. We also note that the commenter did not provide a rationale as to why this clinical labor time would not be duplicative. We continue to agree with the RUC-recommended clinical labor times that we proposed for the four codes in this family.

Comment: A commenter stated that the clinical labor time assigned to CPT codes 62369 and 62370 for clinical staff time during the procedure (the intraservice time) should not be set as the same time as the time assigned for physician intraservice work. The commenter stated that the clinical staff spends significant amounts of time before and after the physician provides his/her services, including tracking patient refill dates, reviewing charts, writing prescriptions, and transmitting them to a pharmacy. The commenter stated that when medications are received, these need to be recorded and double-locked per Drug Enforcement Agency (DEA) regulations, and then when taken out and dispensed the staff

must inform and assist the patient in collecting their signatures. The commenter stated that this clinical labor occurs for every patient encounter and should be recognized in the RVUs assigned to these services.

Response: We agree with the commenter that these are important tasks that must be carried out for each patient and they should be recognized in the valuation of these services. However, we note for the commenter that most of these clinical labor tasks are already included in the typically billed same day E/M code for CPT code 62370, which has clinical labor time allocated for these very same activities, such as checking tab test results, reviewing document history, and coordinating home care. In the case of CPT code 62369, which is not typically billed with a same day E/M code, clinical labor for performing these tasks has been retained in the proposed direct PE inputs.

After consideration of the public comments, we are finalizing the direct PE inputs for the codes in the Electronic Analysis of Implanted Pump family as proposed. We did not propose and we are not finalizing any changes to the current work RVUs.

(25) Somatic Nerve Injection (CPT Codes 64400, 64408, 64415, 64416, 64417, 64420, 64421, 64425, 64430, 64435, 64445, 64446, 64447, 64448, 64449, and 64450)

In May 2018, the CPT Editorial Panel approved the revision of descriptors and guidelines for the codes in this family and the deletion of three CPT codes to clarify reporting (that is, separate reporting of imaging guidance, number of units and a change from a 0-day global to ZZZ for one of the CPT codes in this family). This family of services describe the injection of an anesthetic agent(s) and/or steroid into a nerve plexus, nerve, or branch; reported once per nerve plexus, nerve, or branch as described in the descriptor regardless of the number of injections performed along the nerve plexus, nerve, or branch described by the code.

CPT codes 64400 (*Injection(s), anesthetic agent(s); trigeminal nerve, each branch (i.e., ophthalmic, maxillary, mandibular)), 64408 (Injection(s), anesthetic agent(s), and/or steroid; vagus nerve*), 64415 (*Injection(s), anesthetic agent(s) and/or steroid; brachial plexus), 64416 (Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement)*), 64417 (*Injection(s), anesthetic agent(s) and/or steroid; axillary nerve), 64420 (Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level*), 64421 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerves, each additional level (List separately in addition to code for primary procedure*)), 64425 (*Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves*), 64430 (*Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve), 64435 (Injection(s), anesthetic agent(s) and/or steroid; paracervical (uterine) nerve*), 64445 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve*), 64446 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)*), 64447 (*Injection(s), anesthetic agent(s); femoral nerve*), 64448 (*Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement)*), 64449 (*Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)*), and 64450 (*Injection(s), anesthetic agent(s); other peripheral nerve or branch*) were reviewed for work and PE at the October 2018 RUC meeting. The PE for CPT code 64450 was re-reviewed during the RUC January 2019 meeting.

During the October 2018 RUC presentation for this family of services, the specialty societies stated that CPT codes 64415, 64416, 64417, 64446, 66447, and 64448 were reported with CPT code 76942 (*Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation)* more than 50 percent of the time. Specifically, 76 percent with CPT code 64415, 85 percent with CPT code 64416, 68 percent with CPT code 64417, 77 percent with CPT code 64446, 77 percent with CPT code 66447, and 79 percent with CPT code 64448. It was also noted in the RUC recommendations that this overlap was accounted for in the RUC recommendations submitted for these services. Furthermore, the RUC recommendations sated that the RUC referred CPT codes 64415, 64416, 64417, 64446, 64447 and 64448 to be bundled with ultrasound guidance, CPT code 76942 to the CPT Editorial Panel for CPT 2021.

In reviewing this family of services, our proposed work and PE values for CPT codes 64415, 64416, 64417, 64446, 64447 and 64448 did not consider the overlap of imaging, as noted in the RUC recommendations. We noted that the RUC recommendations did not include values to support the valuation for the bundling of imaging in their work or PE recommendations and that the CPT code descriptors do not state that imaging is included.

For CY 2020, we proposed the RUC-recommended work RVUs for CPT codes 64417 (work RVU of 1.27), 64435 (work RVU of 0.75), 64447 (work RVU of 1.10), and 64450 (work RVU of 0.75), the RUC reaffirmed work RVU of 0.94 for CPT code 64405 (*Injection, anesthetic agent; greater occipital nerve*), which is the current work RVU finalized in the CY 2019 PFS final rule (83 FR 59542), and the RUC reaffirmed work RVU of 1.10 for CPT code 64418 (*Injection, anesthetic agent; suprascapular nerve*), which is the current work RVU value finalized in the CY 2018 PFS final rule (82 FR 53054). Although we proposed the RUC-reaffirmed work RVUs for these two codes, as submitted in the RUC recommendations, we noted that comparable codes in this family of services have lower work RVUs. Thus, these two codes may have become misvalued since their last valuation, as they were not resurveyed under this code family during the October 2018 RUC meeting.

In continuing our review of this code family, we disagreed with the RUC-recommended work RVU of 1.00 for CPT code 64400 and proposed a work RVU of 0.75, to maintain rank order in this code family. Our proposed work RVU is based on a crosswalk to another code in this family, CPT code 64450, which has an identical work RVU of 0.75 and near identical intraservice and total time values to CPT code 64400.

We noted that the RUC-recommended intraservice time decreased from 37 to 6 minutes (84 percent reduction) and the RUC-recommended total time decreased from 69 to 20 minutes (71 percent reduction) for CPT code 64400. However, the RUC-recommended work RVU only decreased by 0.11, a 10 percent reduction. We did not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64400, we believe that it would be more accurate to propose a work RVU of 0.75

based on a crosswalk to CPT code 64450, which has an identical work RVU of 0.75 and near identical intraservice and total times to CPT code 64400. We further noted that our proposed work RVU maintains rank order in this code family among comparable codes.

For CPT code 64408, we disagreed with the RUC-recommended work RVU of 0.90 and proposed a work RVU of 0.75, to maintain rank order in this code family. Our proposed work RVU is based on a crosswalk to another code in this family, CPT code 64450, which has an identical work RVU of 0.75, and near identical intraservice and total time values to CPT code 64408.

We noted that the RUC-recommended intraservice time decreased from 16 to 5 minutes (69 percent reduction) and RUC-recommended total time decreased from 36 to 20 minutes (44 percent reduction) for CPT code 64408. Although the RUC-recommended work RVU decreased by 0.51, a 36 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounted for the substantial reductions in the surveyed work times for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64408, we believe that it would be more accurate to propose a work RVU of 0.75, based on a crosswalk CPT code 64450, to account for these decrease in the surveyed work times. We further noted that our proposed work RVU maintains rank order in this code family among comparable codes.

For CPT code 64415, we disagreed with the RUC-recommended work RVU of 1.42 and proposed a work RVU of 1.35, based on our total time ratio methodology and further supported by a reference to CPT code 49450 (*Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injections(s), image documentation and report*), which has a work RVU of 1.36 and similar intraservice and total time values to CPT code 64415.

We noted that the RUC-recommended intraservice time decreased from 15 to 12 minutes (20 percent reduction) and RUC-recommended total time decreased from 44 to 40 minutes (9 percent reduction). However, the RUC-recommended work RVU only decreased by 0.06, which is a 4 percent reduction. We did not believe the RUC-recommended work RVU appropriately accounted for the substantial reductions in the surveyed work times for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64415, we believed that it would be more accurate to propose a work RVU of 1.35, based on our time ratio methodology and a reference to CPT code 49450, to account for these decrease in the surveyed work times.

For CPT code 64416, we disagreed with the RUC-recommended work RVU of 1.81 and proposed a work RVU of 1.48, based on our total time ratio methodology and further supported by a bracket of CPT code 62270 (*Spinal puncture, lumbar, diagnostic*), which has a work RVU of 1.37, identical intraservice, and similar total time to CPT code 64416 and CPT code 91035 (*Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation*), which has a work RVU of 1.59, identical intraservice, and near identical total time values to CPT code 64416.

We noted that while the RUC-recommended intraservice time remained unchanged, the RUC-recommended total time decreased from 60 to 49 minutes (18 percent reduction). However, the RUC recommended maintaining the current work RVU of 1.81. We do not believe the RUC-recommended work RVU appropriately accounted for the substantial reductions in the surveyed total time for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believed that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64416, we believed that it would be more accurate to propose a work RVU of 1.48, based on our time ratios methodology and supported by a bracket to CPT code 62270 and CPT code 91035, to account for these decreases in the surveyed work times.

For CPT code 64420, we disagreed with the RUC-recommended work RVU of 1.18 and proposed a work RVU of 1.08, based on our time ratio methodology and further supported by a reference to CPT code 12011 (*Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.5 cm or less*), which has a work RVU of 1.07 and similar intraservice and total time values to CPT code 64420.

We noted that the RUC-recommended intraservice time decreased from 17 to 10 minutes (41 percent reduction) and the RUC-recommended total time decreased from 37 to 34 minutes (8 percent reduction). However, the RUC recommended to maintaining the current work RVU of 1.18. We do not believe the RUC-recommended work RVU appropriately accounted for the substantial reductions in the surveyed work times for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64420, we believed that it would be more accurate to propose a work RVU of 1.08 based on our times ratio methodology and a crosswalk to CPT code 12011, to account for these decreases in the surveyed work times.

For CPT code 64421, we disagreed with the RUC-recommended work RVU of 0.60 and proposed a work RVU of 0.50, based on our intraservice time ratio methodology and to maintain rank order among comparable codes in the family. Our proposed work RVU is further supported by a crosswalk to CPT code 15276 (*Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)*), which has a work RVU of 0.50 and identical intraservice and total times to CPT code 64421.

We noted that our time ratio methodology suggests the code is better valued at 0.50. Furthermore, we note the RUC-recommended work RVU of 0.60 creates a rank order anomaly in the code

family. In the case of CPT code 64421, we believed that it would be more accurate to propose a work RVU of 0.50, based on our time ratio methodology and a crosswalk to CPT code 15276, to maintain rank order among comparable codes in the family.

For CPT code 64425, we disagreed with the RUC-recommended work RVU of 1.19 and proposed a work RVU of 1.00, to maintain rank order among comparable codes in the family, based on a bracket of CPT code 12001 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 2.5 cm or less*) which has a work RVU of 0.84 and near identical intraservice and total time values to CPT code 64425 and CPT code 30901 (*Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method*), which has a work RVU of 1.10 and near identical intraservice and total times to CPT code 64425. CPT code 64425 has 11 minutes of intraservice time and 25 minutes of total time.

We noted that the RUC-recommended work RVU of 1.19 creates a rank order anomaly in the code family. In the case of CPT code 64425, we believed that it would be more accurate to propose a work RVU of 1.00, based on a bracket of CPT codes 12001 and 30901 to maintain rank order among comparable codes in the family.

For CPT code 64430, we disagreed with the RUC-recommended work RVU of 1.15 and proposed a work RVU of 1.00, to maintain rank order among comparable codes in the family, based on a bracket of CPT code 45330 (*Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*), which has a work RVU of 0.84 and near identical intraservice and total time values to CPT code 64430 and CPT code 31576 (*Laryngoscopy, flexible; with biopsy(ies)*), which has a work RVU of 1.89 and near identical intraservice and total time values to CPT code 64430.

We noted that the RUC-recommended intraservice time decreased from 17 to 10 minutes (41 percent reduction) and the RUC-recommended total time increased from 39 to 43 minutes (10 percent increase). While the RUC-recommended work RVU is decreasing by 0.31, a 21 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounted for the substantial reductions in the surveyed intraservice work time for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64430, we believed that it would be more accurate to propose a work RVU of 1.00, based on a bracket of CPT codes 45300 and 31576 to account for these decreases in surveyed work times and to maintain rank order among comparable codes in this family.

For CPT code 64445, we disagreed with the RUC-recommended work RVU of 1.18 and proposed a work RVU of 1.00, based on our time ratio methodology and to maintain rank order among comparable codes in the family. Our proposed work RVU is based on a bracket of CPT code 12001 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 2.5 cm or less*), which has a work RVU of 0.84 and near identical intraservice and total times to CPT code 64445 and CPT code 30901 (*Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method*), which has a work RVU of 1.10 and near identical intraservice and total time values to CPT code 64445.

We noted that the RUC-recommended intraservice time decreased from 15 to 10 minutes (33 percent reduction) and the RUC-recommended total time decreased from 48 to 24 minutes (50 percent reduction). While the RUC-recommended work RVU is decreasing by 0.30, a 21 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounted for the substantial reductions in the surveyed intraservice work time for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64445, we believed that it would be more accurate to propose a work RVU of 1.00, based on a bracket of CPT codes 12001 and 30901 to account for these decreases in surveyed work times and to maintain rank order among comparable codes in the family.

For CPT code 64446, we disagreed with the RUC-recommended work RVU of 1.54 and proposed a work RVU of 1.36 based on our intraservice time ratios methodology and further supported by a reference to CPT code 51710 (*Change of cystostomy tube; complicated*), which has a near identical work RVU of 1.35 and near identical intraservice and total time values to CPT code 64446.

We noted that RUC-recommended intraservice time decreased from 20 to 15 minutes (25 percent reduction) and the RUC-recommended total time decreased from 64 to 40 minutes (38 percent reduction). While the RUC-recommended work RVU is decreasing by 0.27, a 15 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounted for the substantial reductions in the surveyed intraservice work time for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64446, we believed that it would be more accurate to propose a work RVU of 1.36, based on our time ratios methodology and a reference to CPT code 51710 to account for these decreases in surveyed times and to maintain rank order among comparable codes in the family.

For CPT code 64448, we disagreed with the RUC-recommended work RVU of 1.55 and proposed a work RVU of 1.41, based our intraservice time ratio methodology and a reference to CPT code 27096 (*Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed*), which has a work RVU of 1.48 and near identical intraservice time and identical total time values to CPT code 64448.

We noted that RUC-recommended intraservice time decreased from 15 to 13 minutes (13 percent reduction) and the RUC-recommended total time decreased from 55 to 38 minutes (62 percent reduction). While the RUC-recommended work RVU is only decreasing by 0.08, which is only a 5 percent reduction. We do not believe the RUC-recommended work RVU appropriately accounted for the substantial reductions in the surveyed intraservice work time for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a

one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64448, we believed that it would be more accurate to propose a work RVU of 1.41, based on our time ratios methodology and a crosswalk to CPT code 27096 to account for these decreases in surveyed times and to maintain rank order among comparable codes in the family.

For CPT code 64449, we disagreed with the RUC-recommended work RVU of 1.55 and proposed a work RVU of 1.27, based our intraservice time ratio methodology and a reference to CPT code 11755 (*Biopsy of nail unit (e.g., plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)*), which has a work RVU of 1.25 and near identical intraservice and total times to CPT code 64449.

We noted that RUC-recommended intraservice time decreased from 20 to 14 minutes (30 percent reduction) and the RUC-recommended total time decreased from 60 to 38 minutes (37 percent reduction). While the RUC-recommended work RVU is decreasing by 0.26, a 14 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounted for the substantial reductions in the surveyed intraservice work time for the procedure. Although we did not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64449, we believe that it would be more accurate to propose a work RVU of 1.27, based on our time ratios methodology and a reference to CPT code 11755 to account for these decreases in surveyed times and to maintain rank order among comparable codes in the family.

For the direct PE inputs, we proposed to remove the clinical labor time for the ''Confirm availability of prior images/studies'' (CA006) activity for CPT code 64450. This code does not currently include this clinical labor time, and unlike the new code, CPT code 64XX1, in the Genicular Injection and RFA code family, in which the PE for CPT code 64450 was resurveyed at the January 2019 RUC for PE, CPT code 64450 does not include imaging guidance in its code descriptor. When CPT code 64450 is performed with imaging guidance, it would be billed together with a separate imaging code that already includes clinical labor time for confirming the availability of prior images. As a result, it would be duplicative to include this clinical labor time in CPT code 64450. We are also proposing to refine the clinical labor time for the ''*Assist physician or other qualified healthcare professional—directly related to physician work time (100 percent)*'' (CA018) activity from 10 to 5 minutes for CPT code 64450, to match the intraservice work time and proposing to refine the equipment times in accordance with our standard equipment time formulas for CPT code 64450.

Additionally, we proposed to refine the clinical labor time for the ''provide education/obtain consent'' (CA011) from 3 minutes to 2 minutes, for CPT codes 64400, 64408, 64415, 64417, 64420, 64425, 64430, 64435, 64445, 64447 and 64450, to conform to the standard for this clinical labor task. We are also proposing to refine the equipment time in accordance with our standard equipment time formula for these codes. We note that there were no RUC-recommended direct PE inputs provided for CPT codes 64416, 64446, and 64448.

We received public comments on the proposed valuation of the codes in the Somatic Nerve Injection family. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they supported our proposal of the RUC-recommended work RVUs for CPT codes 64417, 64435, 64447, and 64450 and the RUC- reaffirmed work RVUs for CPT codes 64405 and 64418.

Response: We appreciate the support for our proposals from commenters. As noted above, although we proposed the RUC-reaffirmed work RVUs for 64405 and 64418, as submitted in the RUC recommendations, we reiterate that comparable codes in this family of services have lower work RVUs. Thus, we are considering whether these two codes may have become misvalued since their last valuation, as they were not resurveyed under this code family during the October 2018 RUC meeting.

Comment: Several commenters disagreed with the proposed work RVUs for CPT codes 64415, 64416, 64446, 64448, 64449. Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for these procedures. Commenters stated that CMS based the proposed values for these services on what the commenters referred to as the ''CMS time ratio methodology''; however, the agency did not elaborate on which time ratio specifically. Commenters speculated on the time ratio methodology they believed CMS applied to value the codes where the time ratio methodology used was not explicitly stated.

Several commenters disagreed with the use of time ratio methodologies for work valuation of these services. Commenters stated that this use of time ratios is not a valid methodology for valuation of physicians' services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying time ratio methodologies to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. Commenters suggested that, in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters urged CMS to determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Response: We have stated the specific time ratio methodology used to determine the proposed work RVU for each of the codes in this family where it was not explicitly stated in this final rule.

We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys which suggests that the amount of time involved in furnishing the service has changed significantly. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Based on

the aforementioned crosswalks, brackets, or references for CPT codes 64415, 64416, 64446, 64448, 64449 codes, we continue to believe that the proposed values for these codes better maintain the relative intensity of the codes in the family, and better preserves relativity with the rest of the codes on the PFS.

Comment: Several commenters disagreed with the proposed work RVUs for CPT codes 64420 and 64421. Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for these procedures. Commenters stated that CMS based the proposed values for these services on what the commenters referred to as the ''CMS time ratio methodology'', however, the Agency did not elaborate on which time ratio specifically. Commenters speculated the time ratio methodology they believed CMS applied to value these codes.

Several commenters disagreed with the use of time ratio methodologies for work valuation of these services. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. Commenters noted that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters urged CMS to determine the work valuation for the each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Several commenters disagreed with our reference to older work time sources, and noted that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource-based. Commenters stated that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: In this final rule we have stated the specific time ratio methodology used to determine the CMS proposed work RVU for each of the codes in this family where it was not explicitly stated.

We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274).

We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Based on the aforementioned crosswalks, brackets, or references for these codes, which continue to believe the proposed values better maintains the relative intensity of the codes in the family, and better preserves relativity with the rest of the codes on the PFS.

Comment: A commenter noted that CMS did not state the current times for CPT code 64425. Several commenters disagreed with the proposed work RVUs for CPT Codes 64400, 64408, 64425, and 64430). Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for these procedures. Commenters disagreed with our reference to the older work time sources, and suggested that the use of those sources led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, in this case, were not surveyed, and therefore, were not resource-based. Commenters noted that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC for the services.

Response: We have included the times for CPT code 64425 in the discussion above on this code in this final rule, to note that this code has 11 minutes of intraservice time and 25 minutes of total time. We appreciate the commenters' concerns regarding our reference to older work time sources and their use in the code valuation process for establishing work RVUs for these services. We agree that it is important to use the recent data available regarding work times, and we recognize that when many years have passed since time was last measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Based on the aforementioned crosswalks, brackets, or references for these codes, which continue to believe the proposed values better maintains the relative intensity of the codes in the family, and better preserves relativity with the rest of the codes on the PFS.

Comment: Several commenters disagreed with the proposed work RVUs for CPT codes 64415, 64416, 64446, 64448, and 64449. Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for these procedures.

Several commenters disagreed with the use of time ratio methodologies for work valuation of these services. Commenters stated that this use of time ratios is not a valid methodology for

valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. Commenters suggested that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters urged CMS to determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Response: We disagree with the commenters that the use of time ratios is not a valid valuation methodology, and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Based on the aforementioned crosswalks, brackets, or references for these codes, which continue to believe the proposed values better maintains the relative intensity of the codes in the family, and better preserves relativity with the rest of the codes on the PFS.

Comment: Several commenters disagreed with the proposed work RVU of 1.00 for CPT code 64445. Commenters stated that CMS should instead finalize the RUC-recommended work RVU of 1.10 for this procedure. A commenter stated that the CMS proposed value of 1.00 seemingly was selected using a method with no precedent.

Response: We disagree with the commenter's suggestion that the CMS-proposed value was selected using an unprecedented method. As stated in the CY 2020 PFS proposed rule (84 FR 40582), the proposed work RVU was selected to maintain rank order among comparable codes in the family. The proposed work RVU was further supported by a bracket to CPT codes 12001 and 30901. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). For additional information on our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Based on the aforementioned brackets, which continue to believe the proposed value better maintains the relative intensity of the codes in the family, and better preserves relativity with the rest of the codes on the PFS.

Comment: A few commenters disagreed with the proposed direct PE refinements to refine the clinical labor time for the ''provide education/obtain consent'' (CA011) from 3 minutes to 2 minutes, for CPT codes 64400, 64408, 64415, 64417, 64420, 64425, 64430, 64435, 64445, 64447 and 64450, to conform to the standard for this clinical labor task. The also disagreed with the proposal to refine the equipment time in accordance with our standard equipment time formula for these codes. Commenters stated that the RUC does not have a standard time for this task. This time is required because of the potential complications associated with injections and the need to review aftercare instructions.

Response: We disagree with the commenters that 3 minutes would be typically needed for the clinical staff to provide education and obtain consent in these procedures. We have typically assigned 2 minutes for this clinical labor activity unless we had a specific rationale for a higher amount of clinical labor time, and we continue to believe that this standard amount of clinical labor time would be the most accurate value for CPT codes 64400, 64408, 64415, 64417, 64420, 64425, 64430, 64435, 64445, 64447 and 64450. Furthermore, we note that these codes have 2 minutes of ''Review home care instructions, coordinate visits/ prescriptions'' (CA035).

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Somatic Nerve Injection family as proposed.

(26) Genicular Injection and RFA (CPT Codes 64640, 64454, and 64624)

In May 2018, the CPT Editorial Panel approved the addition of two codes to report injection of anesthetic and destruction of genicular nerves by neurolytic agent. In October 2018, the RUC discussed issues surrounding the survey of this family of services and supported the specialty societies' request for CPT codes 64640 (*Destruction by neurolytic agent; other peripheral nerve or branch*), 64454 (*Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches including imaging guidance, when performed*), and 64624 (*Destruction by neurolytic agent genicular nerve branches including imaging guidance, when performed*) to be resurveyed and presented at the January 2019 RUC meeting, based on their concern that many survey respondents appeared to be confused about the number of nerve branch injections involved with these three codes. The RUC resurveyed these services at the January 2019 RUC meeting.

For CY 2020, we proposed the RUC-recommended work RVUs for two of the three codes in this family. We proposed the RUC-recommended work RVU of 1.98 (25th percentile survey value) for CPT code 64640 and the RUC-recommended work RVU of 1.52 (25th percentile survey value) for CPT code of 64454.

For CPT code 64624, we disagreed with the RUC-recommended work RVU of 2.62, which is higher than the 25th percentile survey value, a work RVU 2.50, and proposed a work RVU of 2.50 (25th percentile survey value) based on a reference to CPT code 11622 (*Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 1.1 to 2.0 cm*), which has a work RVU of 2.41 and near identical intraservice and total times to CPT code 64624.

In our review of CPT code 64624, we examined the intraservice time ratio for the new code, CPT code 64624, in relation to an existing code in this family of services, CPT code 64640. CPT code 64624 has a RUC-recommended work RVU of 2.62, 25 minutes of intraservice time, and 74 minutes of total time. CPT code 64640 has a RUC-recommended work RVU of 1.98, 20 minutes of intraservice time, and 64 minutes of total time. To derive our proposed work RVU of 2.50, we calculated the intraservice time ratio

between these two codes, which is a calculated value of 1.25, and applied this ratio times the RUC-recommended work RVU of 1.98 for CPT code 64650, which resulted in a calculated value of 2.48. This value is nearly identical to the January 2018 RUC 25th percentile survey value for CPT code 64624, a work RVU of 2.50. Our proposed work RVU of 2.50 is further supported by a reference to CPT code 11622.

For the direct PE inputs, we proposed to remove the clinical labor time for the ''Confirm availability of prior images/studies'' (CA006) activity for CPT code 64640. This code does not currently include this clinical labor time, and unlike the new code in the family (CPT code 64624), CPT code 64640 does not include imaging guidance in its code descriptor. When CPT code 64640 is performed with imaging guidance, it would be billed together with a separate imaging code that already includes clinical labor time for confirming the availability of prior images. As a result, it would be duplicative to include this clinical labor time in CPT code 64640. We proposed to refine the clinical labor time for the ''Assist physician or other qualified healthcare professional—directly related to physician work time (100 percent)'' (CA018) activity from 25 to 20 minutes for CPT code 64640, to match the intraservice work time. We are also proposed to refine the equipment times in accordance with our standard equipment time formulas for CPT code 64640.

We proposed the RUC-recommended direct PE inputs for CPT code 64454 without refinement.

For CPT code 64624, we proposed to refine the quantity of the ''cannula (radiofrequency denervation) (SMK–C10)'' (SD011) supply from 3 to 1. We did not believe that the use of 3 of this supply item would be typical for the procedure. We noted that the RUC recommendations for another code in this family, CPT code 64640 only contains 1 of this supply item. We believed that the nerves would typically be ablated one at a time using this cannula, as opposed to ablating three of them simultaneously as suggested in the recommended direct PE inputs. We also searched in the RUC database for other CPT codes that made use of the SD011 supply, and out of the seven codes that currently use this item, none of them include more than 2 cannula. As a result, we proposed to refine the supply quantity to 2 cannula to match the highest amount contained in an existing code on the PFS. We proposed to refine the equipment time for the ''radiofrequency kit for destruction by neurolytic agent'' (EQ354) equipment from 141 minutes to 47 minutes. The equipment time recommendation was predicated on the use of 3 of the SD011 supplies for 47 minutes apiece, and we proposed to refine the equipment time to reflect our supply refinement to 1 cannula. It was unclear in the RUC recommendation materials as to whether the radiofrequency kit equipment was in use simultaneously or sequentially along with the cannula supplies, and therefore, we are soliciting comments on the typical use of this equipment.

We received public comments on the proposed valuation of the codes in the Genicular Injection and RFA family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that for both of the new codes, CPT codes 64454 and 64624, they were concerned that CMS proposed to reduce values recommended by the CPT Relative Value Scale Update Committee (RUC) based primarily upon a comparison to CPT code 64640.

Response: We note that we proposed a different work RVU for one of the two new codes in this family, not both, as noted by the commenter. We proposed a work RVU of 2.50 for CPT code 64454, based upon an intraservice time ratio between that code and CPT code 64640. We proposed the RUC-recommended work RVU of 1.52 for CPT code 64454.

Comment: A commenter stated that they supported our proposal of the RUC-recommended work RVUs for the CPT codes 64640 and 64454, two of the three codes in this family.

Response: We appreciate the support for our proposals from the commenter.

Comment: Several commenters disagreed with the CMS proposed work RVU of 2.50 for CPT code 64624 and stated that CMS should instead finalize the RUC-recommended work RVU of 2.62. A commenter stated that CPT code 64624 describes the destruction of three different nerve branches at three locations to provide analgesia for the respective knee and should not be crosswalked to CPT code 11642 (*Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 1.1 to 2.0 cm*) which describes excision of a malignant lesion. This commenter further noted that the RUC direct crosswalk, CPT code 11642 requires the same time as CMS' proposed crosswalk code 11622. However, CPT code 11622 requires less physician work because it is an excision on the trunk, arms or legs, whereas CPT code 11642 is an excision on the face, ears, eyelids, nose, lips, which is a more delicate area in which precision is required and it is more intense and complex to complete. CPT code 64624 likewise is more intense, complex and requires precision to avoid irreversible damage.

Response: We note that the commenter stated the RUC's crosswalk in reference to what code CPT code 64424 should not be crosswalked to, perhaps the commenter meant to note the CMS reference code, CPT code 11622. We agree with the commenter that CPT code 64624 should not be crosswalked to CPT code 11622, which is why we proposed this code as a reference, and not a direct crosswalk. Furthermore, we disagree that RUC crosswalk, CPT code 11642, requires the same times as CMS' proposed crosswalk, 11622.

We disagree with the commenters that there is a meaningful difference in intensity between CPT reference code, CPT code 11622 and RUC's crosswalk CPT 11642. These two codes share the identical work times, the same intraservice time of 30 minutes and same total time, 68 minutes. We continue to believe that it was more accurate to propose a work RVU of 2.50 for CPT code 64624, based on the reference to CPT code 11622, further supported by the survey 25th percentile value, a work RVU of 2.50. We believe the proposed value better maintains the relative intensity of the two codes in the family, and better preserves relativity with the rest of the codes on the PFS.

Comment: Several commenters disagreed with the CMS proposal to refine the quantity of the ''cannula (radiofrequency denervation) (SMK–C10)'' (SD011) supply from 3 to 1 for CPT code 64624. Commenters stated that, as with the sacroiliac joint code, CPT code 64624 does require simultaneous ablation of the three genicular nerves. Commenters further noted that this is standard practice, and therefore, was the way the survey respondents would have completed the survey.

Response: We appreciate the additional information provided by the commenters regarding the SD011 cannula supply. We continue to have reservations as to whether three simultaneous ablations would be typical for this procedure; however, we are finalizing a supply quantity of 3 cannula (SD011) for CPT code 64624 as recommended by commenters.

Comment: Several commenters disagreed with the CMS proposal to refine the equipment time for the ''radiofrequency kit for destruction by neurolytic agent'' (EQ354) equipment from 141 minutes to 47 minutes. Commenters stated that three kits are

used for 47 minutes each totaling 141 minutes, as the 47 minutes (times 3) occurs simultaneously. Commenters stated again that three cannulas and three kits are needed for the simultaneous ablation of three nerves.

Response: Since we did not finalize our proposal to refine the quantity of the SD011 cannula supply from 3 to 1 for CPT code 64624, we are also not finalizing our refinement to the equipment time for EQ354. We will instead finalize the RUC-recommended equipment time of 141 minutes for the radiofrequency kit (EQ354).

After consideration of the public comments, we are finalizing the work RVUs for the codes in the Genicular Injection and RFA family as proposed. We are also finalizing the RUC-recommended direct PE inputs for the codes in this family, with the exception of finalizing a supply quantity of 3 of SD011 and 141 minutes for EQ354 for CPT code 64624, as recommended by commenters.

(27) Cyclophotocoagulation (CPT Codes 66711, 66982, 66983, 66984, 66987, and 66988)

In October 2017, CPT codes 66711 (*Ciliary body destruction; cyclophotocoagulation, endoscopic*) and 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification*) were identified as codes reported together 75 percent of the time or more. The RUC reviewed action plans to determine whether a code bundle solution should be developed for these services. In January 2018, the RUC recommended to refer to CPT to bundle 66711 with 66984 for CPT 2020. In May 2018, the CPT Editorial Panel revised three codes and created two new codes, CPT codes 66987 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation*) and 66988 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation*) to differentiate cataract procedures performed with and without endoscopic cyclophotocoagulation.

The codes discussed above and CPT codes 66982 *(Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage*) and 66983 *(Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure))* were reviewed at the January 2019 RUC meeting.

For CY 2020, we proposed the RUC-recommended work RVU of 10.25 for CPT code 66982, the RUC recommendation to contractor-price CPT code 66983, and the RUC-recommended work RVU of 7.35 for CPT code 66984. We disagreed with the RUC recommendations for CPT codes 66711, 66987, and 66988.

For CPT code 66711, we disagreed with the RUC-recommended work RVU of 6.36 and proposed a work RVU of 5.62, based on crosswalk to CPT code 28285 (*Correction, hammertoe (e.g., interphalangeal fusion, partial or total phalangectomy*), which has an identical work RVU of 5.62, and similar intraservice and total times.

In our review of CPT code 66711, we noted that the recommended intraservice time is decreasing from 20 minutes to 10 minutes (33 percent reduction), and that the recommended total time is decreasing from 192 minutes to 191 minutes (0.5 percent reduction). While the RUC-recommended work RVU is decreasing from 7.93 to 6.36, which is a 20 percent reduction, we do not believe it appropriately accounts for the decreases in survey time. Time ratio methodology suggest that CPT code 66711 is better valued at a work RVU of 5.29, thus it is overvalued with consideration to the decreases in survey times. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 66711, we believed that it would be more accurate to propose a work RVU of 5.62, based on our time ratio methodology and a crosswalk to CPT code 28285 to account for these decreases in surveyed work times.

For CPT code 66987, the RUC recommended a work RVU of 13.15, we disagreed with the RUC-recommended work RVU and proposed contractor-pricing for this code. In reviewing this code, we noted that the RUC recommendation survey values did not support the RUC-recommended work RVU of 13.15 and furthermore, the RUC recommendations did not include a crosswalk to support the RUC-recommended work RVU. The RUC recommendations noted a lack of potential crosswalk codes due to the complete lack of similarly intense major surgical procedures comparable in the amount of skin-to-skin time, operating room time and amount of post-operative care. We note that the RUC-recommended work RVU of 13.15 is higher than similarly timed codes on the PFS. Given that lack of both survey data and a crosswalk to support the RUC-recommended work RVU for this new code, and that the RUC-recommended work RVU of 13.15 is higher than similarly timed codes on the PFS, we believed it is was appropriate to propose contractor-pricing for CPT code 66987. We also noted that the RUC recommended contractor-pricing for another code in this family, CPT code 66983, which we proposed to contractor-price for CY 2020.

For CPT code 66988, the RUC recommended a work RVU of 10.25, we disagreed with the RUC-recommended work RVU and proposed contractor-pricing for this code. In reviewing this code, we noted that the RUC recommendation survey values do not support the RUC-recommended work RVU of 10.25. Furthermore, we were concerned with the RUC recommended crosswalk, CPT code 67110 (*Repair of retinal detachment; by injection of air or other gas (e.g., pneumatic retinopexy*), which is the same crosswalk used to support the RUC-recommended work RVU of 10.25 for another code in this family, CPT code 66982. CPT code 67110 has 30 minutes of intraservice time and 196 minutes of total time. Although CPT code 67110 has the identical intraservice time to CPT codes 66982 and 66988, we note that CPT code 67110 has 196 minutes of total time, which is 21 minutes less than the 175 minutes of total time of CPT code 66982, and 6 minutes less than the 202 minutes of total time of CPT Code 66988. However, the RUC is recommending the same work RVU of 10.25 for CPT codes 66982 and 66988, supported by the same crosswalk to CPT code 67110.

Given that lack of survey data and our concern for the RUC-recommended crosswalk to support the RUC-recommended work RVU of 10.25 for CPT code 66988, we believed it was appropriate to propose contractor-pricing for CPT code 66988. We also noted that the RUC recommended contractor-pricing for another code in this family, CPT code 66983, which we are prosed for CY 2020.

We proposed to remove all the direct PE inputs for CPT codes 66987 and 66988, given our proposal to contractor-price these codes. We proposed the RUC-recommended direct PE inputs for the other codes in this family.

We received public comments on the proposed valuation of the codes in the Cyclophotocoagulation family. The following is a summary of the comments we received and our responses.

Comment: A commenter noted that for CPT code 66711, the intra-service time is decreasing from 30 minutes to 20 minutes, not 20 minutes to 10 minutes, as stated by CMS in the proposed rule.

Response: We apologize for the typo and in this final rule corrected the intraservice time value for CPT code 66711 in the discussion above on this code, to reflect a decrease in intraservice time from 30 minutes to 20 minutes.

Comment: Several commenters stated support for our proposal of the RUC-recommended work RVU for CPT code 66982, the RUC recommendation to contractor-price CPT code 66983, and the RUC-recommended work RVU for CPT code 66984.

Comment: Several commenters stated support for our proposal of the RUC-recommended work RVU for CPT code 66982, the RUC recommendation to contractor-price CPT code 66983, and the RUC-recommended work RVU for CPT code 66984.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation for CPT code 66711. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters urged CMS to determine the work valuation for the each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Response: We appreciate the commenters' concerns regarding CMS' use of time ratio methodologies in the code valuation process for establishing work RVUs. We have responded to concerns about our methodology earlier in this section of this final rule. For additional information regarding the use of use of time ratios in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the CMS proposed work RVU of 5.62 for CPT code 66711 and stated that CMS should instead finalize the RUC-recommended work RVU of 6.36. Commenters stated that although CPT code 66711 has a similar total time value to the CMS crosswalk CPT code 28285, CPT code 66711 requires more physician work and is much more intense, and complex working in the eye than on a toe. Correction of hammertoe as described by CPT code 28285, is a low-risk procedure on a small appendage, while CPT 66711, endoscopic ciliary photoablation (ECP) is a high-risk procedure on a diseased eye with risk of loss of vision.

It was noted in the RUC's comment letter that they expressed difficulty in finding a valid crosswalk to recommend the appropriate work RVU for CPT code 66711. The RUC further noted that they conducted a thorough search of all other potential crosswalk codes and ran into a lack of potential crosswalk codes due to the lack of similarly intense major surgical procedures with a comparable amount of skin-to-skin time, OR time and amount of post-operative care. They noted that the most appropriate crosswalk for CPT 66711 is CPT code 67210 Destruction of localized lesion of retina (*e.g.,* macular edema, tumors), 1 or more sessions; photocoagulation (work RVU = 6.36 and 15 minutes intra-service time). CPT code 66711 is more intense and complex to perform than 67210 on all measures examined (mental effort/judgment, technical skill/physical effort and psychological stress); both codes use laser ablation of tissue making it the most clinically relatable service for comparison.

Response: We disagree with the commenters that there is a meaningful difference in intensity between CPT code 66711 and the CMS crosswalk CPT code 28285. These two codes share an identical intraservice time of 30 minutes and differ by only 2 minutes of total time, 192 minutes for CPT code 66711, compared to 190 minutes for CPT code 28285. Given the minimal difference in intensity between these two codes, it would be difficult for two procedures to match more closely on intensity (which is itself a derived number not measured directly) without sharing the same work times. Like CPT code 66711, the CMS crosswalk, CPT code 28285, is a significant 090-day global procedure that requires 30 minutes of intraservice work time. We continue to believe that it is more accurate to propose a work RVU of 5.62 for CPT code 66711, based on the aforementioned crosswalk to CPT code 28285, which we believe better preserves relativity with the rest of the codes on the PFS. Furthermore, the CMS crosswalk code (CPT code 28285) was found after a thorough search of valid crosswalks to recommend the appropriate work RVU for CPT code 66711, which we reiterate is significant 090-day global procedure that requires 30 minutes of intraservice work time, the same as CPT code 66711.

Comment: Several commenters disagreed with the CMS proposal to contractor-price CPT code 66987 and stated that CMS should instead finalize the RUC-recommended work RVU of 13.15. Several commenters stated that contractor-pricing would be burdensome. One commenter noted that contractor-pricing would be burdensome because CPT code 66987 and CPT code 66987 (CMS proposed contractor-pricing) would be reported over 7,000 times per year.

Response: We thank commenters for their feedback. We note that the RUC-recommended contractor-pricing for another code in this family, CPT code 66983, and did not make a general or specific reference to burden related to contractor-pricing. Furthermore, we note that when services are furnished to a Medicare beneficiary, the provider files the Medicare claim with the contractor that has jurisdiction over the claims furnished by the provider. We are not persuaded by commenter's assertion that contractor-pricing for CPT code 66987 would lead to an increase in burden.

Comment: The RUC's comment letter noted that they had challenges of surveying these intense 090-day global services with short intra-service time due a lack of similar reference services. One commenter stated that CMS recommend contractor-pricing for CPT code 66987, despite survey data that

supports the RUC-recommended value for this code.

Response: As stated in the proposed rule, the RUC-recommended work RVU of 13.50, lacked support from survey data and a crosswalk to support the value. Furthermore, the RUC-recommended a work RVU of 13.50, but the survey 25 percentile value was 13.50, and the RUC-recommended work RVU is higher than similarly timed codes on the PFS. Therefore, we believe it is more appropriate to contractor-price this code until more data can be collected, for consideration in future rulemaking.

Comment: Several commenters disagreed with the CMS proposal to contractor-price CPT code 66988 and stated that CMS should instead finalize the RUC-recommended work RVU of 10.25. Several commenters stated that contractor-pricing would be burdensome. One commenter noted that contractor-pricing would be burdensome because CPT code 66988 and CPT code 66987 (CMS proposed contractor-pricing) would be reported over 7,000 times per year.

Response: We thank commenters for their feedback. We note that the RUC-recommended carrier-pricing for another code in this family, CPT code 66983, and did not make general or specific reference to burden related to contractor-pricing. Furthermore, we note that when services are furnished to a Medicare beneficiary, the provider files the Medicare claim with the contractor that has jurisdiction over the claims furnished by the provider. We are not persuaded by the commenter's discussion that contractor-pricing for CPT code 66988 would lead to an increase in burden.

Comment: One commenter stated that CMS recommended contractor-pricing for CPT code 66988, despite survey data that supports the RUC-recommended value for this code.

Response: As stated in the proposed rule, the RUC-recommended work RVU of 10.25, lacked support from survey data and a crosswalk to support the value. Furthermore, the RUC-recommended a work RVU of 10.25 but the survey 25 percentile value was 11.08. Furthermore, CMS noted concerns with the RUC's crosswalk (CPT code 67710) to support their work RVU for this code. To reiterate, although CPT code 67110 has the identical intraservice time to CPT codes 66982 and 66988, we note that CPT code 67110 has 196 minutes of total time, which is 21 minutes less than the 175 minutes of total time of CPT code 66982, and 6 minutes less than the 202 minutes of total time of CPT Code 66988. However, the RUC is recommended the same work RVU of 10.25 for CPT codes 66982 and 66988, supported by the same crosswalk to CPT code 67110, which we found concerning. Therefore, we believe it is more appropriate to contractor-price this code until more data can be collected, for consideration in future rulemaking.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Cyclophotocoagulation family as proposed.

(28) X-Ray Exam—Sinuses (CPT Codes 70210 and 70220)

CPT code 70210 (*Radiologic examination, sinuses, paranasal, less than 3 views*) and CPT code 70220 (*Radiologic examination, sinuses, paranasal, complete, minimum of 3 views*) were identified as potentially misvalued through a screen for Medicare services with utilization of 30,000 or more annually. These two codes were first reviewed by the RUC in April 2018, but were subsequently surveyed by the specialty societies and reviewed again by the RUC in January 2019.

For CPT code 70210, we disagreed with the RUC-recommended work RVU of 0.20, and proposed to maintain the current work RVU of 0.17 supported by a bracket of CPT code 73501 (*Radiologic examination, hip, unilateral, with pelvis when performed; 1 view*), which has a work RVU of 0.18, and CPT code 73560 (*Radiologic examination, knee; 1 or 2 views*), which has a work RVU of 0.16.

The RUC's recommendation is consistent with 25th percentile of survey results and is based on a comparison of the survey code with the two key reference services. The first key reference service, CPT code 71046 (*Radiologic examination, chest; 2 views*), has a work RVU of 0.22, 4 minutes of intraservice time, and 6 minutes of total time. The RUC noted that the survey code has 1 minute less intraservice and total time compared with the first key reference service (CPT code 71046), which accounts for the slightly lower work RVU for the survey code. The RUC also compared CPT code 70210 to CPT code 70355 (*Orthopantogram (e.g., panoramic X-ray)*), with a work RVU of 0.20, 5 minutes of intraservice time, and 6 minutes of total time. Although the intraservice and total times are lower for CPT code 70210 than for CPT code 70355, the work is slightly more intense for the survey code, according to the RUC, justifying an identical work RVU of 0.20 for CPT code 70210. We disagreed with the RUC's recommendation to increase the work RVU for CPT code 70210 from the current value (0.17) to 0.20 for two main reasons. First, the total time (5 minutes) for this code has not changed from the current total time and without a corresponding explanation for an increase in valuation despite maintaining the same total time, we were not convinced that the work RVU for this code should increase. In addition, we noted that based on a general comparison of CPT codes with identical intraservice time and total time (approximately 23 comparison codes, excluding those currently under review), a work RVU of 0.20 would establish a new upper threshold among this cohort. Therefore, we proposed to maintain the work RVU of 0.17 for CPT code 70210.

For CPT code 70220, we proposed the RUC-recommended work RVU of 0.22.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the X-Ray Exam—Sinuses family. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they supported our proposal for the direct PE inputs for the codes in this family and our proposal for the RUC-recommended work RVU for CPT code 70220.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters disagreed with the proposed work RVUs for CPT code 70210. Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for this procedure. A commenter stated that the best ''corresponding explanation for an increase in valuation despite maintaining the same total time'' is that the current time and value have no validity for comparison since they are CMS/Other, and were assigned using an unknown methodology. In addition, although total times happen to match, CMS/Other times did not break out pre-service, intra-service, and post-service times which have different intensities. Therefore, the value recommendation is based on the survey, which is supported by the survey times, the comparison with other axial x-ray codes, and the survey times.

Response: We appreciate the commenters' concerns regarding CMS' interpretation of older work time sources and their use in the code valuation process for establishing work RVUs for these services. We agree that it is important to use the recent data

available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Based on the aforementioned crosswalks, brackets, or references for these codes, which continue to believe the proposed values better maintains the relative intensity of the codes in the family, and better preserves relativity with the rest of the codes on the PFS.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the X-Ray Exam—Sinuses as proposed.

(29) X-Ray Exam—Skull (CPT Codes 70250 and 70260)

CPT code 70250 (*Radiologic examination, skull, less than 4 views*) was identified as potentially misvalued through a screen of Medicare services with utilization of 30,000 or more annually. CPT code 70260 (*Radiologic examination, skull; complete, minimum of 4 views*) was included as part of the same family. These two codes were first reviewed by the RUC in April 2018, but were subsequently surveyed by the specialty societies and reviewed by the RUC again in January 2019.

For CPT code 70250 we disagreed with the RUC-recommended work RVU of 0.20 and proposed a work RVU of 0.18 supported by crosswalk to CPT code 73501 (*Radiologic examination, hip, unilateral, with pelvis when performed; 1 view*), which has a work RVU of 0.18, 3 minutes of intraservice time, and 5 minutes of total time,

The RUC-recommended work RVU is bracketed by the top key reference service, CPT code 71046 (*Radiologic examination, chest; 2 views*) with 4 minutes of intraservice time, 6 minutes total time, and a work RVU of 0.22; and key reference service, CPT code 73562 (*Radiologic examination, knee; 3 views*), with intraservice time of 4 minutes, total time of 6 minutes, and a work RVU of 0.18. The RUC noted that while the survey code has less time than CPT code 71046, the work is slightly more intense due to anatomical and contextual complexity. The survey code is also more intense compared with the second key reference service, CPT code 73562, according to the RUC, because of the higher level of technical skill involved in an X-ray of the skull (axial skeleton) compared with an X-ray of the knee (appendicular skeleton). The RUC further indicated that a comparison between the survey code and CPT codes with a work RVU of 0.18 would not be appropriate given the higher level of complexity associated with an X-ray of the skull than with other CPT codes that have similar times. We disagreed with the RUC-recommended work RVU of 0.20 for CPT code 70250. We note that the total time for furnishing the service has decreased by 2 minutes while the description of the work involved in furnishing the service has not changed. This suggests that a value closer to the total time ratio (TTR) calculation (work RVU of 0.17) would be more appropriate. In addition, a search of CPT codes with 3 minutes of intraservice time and 5 minutes of total time indicates that the maximum work RVU for codes with these times is 0.18, meaning that a work RVU of 0.20 would establish a new relative high work RVU for codes with these times. Therefore, we proposed a work RVU of 0.18 for CPT code 70250.

We disagreed with the RUC recommended a work RVU of 0.29 for CPT code 70260 and proposed a work RVU of 0.28 based on an increment between this code and CPT code 70250. Moreover, since we proposed a lower work RVU for the base code for this family (work RVU of 0.18 for CPT code 70250), we believe a lower work RVU for CPT code 70260 is warranted. To identify an alternative value, we calculated the increment between the current work RVU for CPT code 72050 (work RVU of 0.24) and the current work RVU for CPT code 72060 (work RVU of 0.34) and applied it to the CMS proposed work RVU for CPT code 70250 (0.18 + 0.10) to calculate a proposed work RVU of 0.28.

The survey times for furnishing the service are 4 minutes of intraservice time and 7 minutes total time, compared with the current intraservice time and total time of 7 minutes. However, in developing their recommendation, the RUC reduced the total time for this code from 7 minutes to 6 minutes. Although the RUC's recommended work RVU reflects the 25th percentile of survey results, the survey 25th percentile is based on an additional minute of total time compared with the RUC's total time for this CPT code.

We believe that applying this increment is a better reflection of the work time and intensity involved in furnishing CPT code 70260, and therefore, we proposed a work RVU of 0.28 for this service.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the X-Ray Exam—Skull family. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the proposed work RVUs for CPT codes 70250 and 70260. Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for these procedures. Commenters disagreed with our reference to older work time sources, and noted that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, in this case, were not surveyed, and therefore, were not resource-based. Commenters noted that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC for the services.

Response: We appreciate the commenters' concerns regarding CMS' interpretation of older work time sources and their use in the code valuation process for establishing work RVUs for these services. We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Based on the aforementioned crosswalks, brackets, or references for

these codes, which continue to believe the proposed values better maintains the relative intensity of the codes in the family, and better preserves relativity with the rest of the codes on the PFS.

Comment: Several commenters disagreed with the CMS proposed work RVU for CPT 70260. Commenters stated that CMS should instead finalize the RUC-recommended work RVU for this procedure. Commenters stated that the incremental methodology used in valuing these services was flawed; commenters did not agree that it was appropriate to reduce the work RVU for CPT code 72202 from the value proposed by the RUC, while also recalibrating the work relative to the RUC's recommended difference in work between this code and CPT code 72200. Commenters noted that it is imperative to employ RUC survey data to value these codes, and that using an incremental approach in lieu of survey data, strong crosswalks, and input from the practitioners providing these services was unjustified.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the X-Ray Exam—Skull family as proposed.

(30) X-Ray Exam—Neck (CPT Code 70360)

CPT code 70360 (*Radiologic examination; neck, soft tissue*) was identified as potentially misvalued through a screen of CPT codes with annual Medicare utilization of 30,000 or more. CPT code 70360 was first reviewed by the RUC in April 2018 but was subsequently surveyed by the specialty societies and reviewed by the RUC again in January 2019.

For CPT code 70360 we disagreed with the RUC recommended work RVU of 0.20 and recommended a work RVU of 0.18, supported by a crosswalk to CPT code 73552 (*Radiologic examination, femur; minimum 2 views*), which has similar time values and work RVU of 0.18. To support their recommendation, the RUC cited the survey key reference service, CPT code 71046 (*Radiologic examination, chest; 2 views*), with a work RVU of 0.22, 4 minutes of intraservice time, and 6 minutes of total time. They noted that the key reference code has 1 minute higher intraservice and total time, accounting for the slightly higher work RVU compared with the survey code, CPT code 70360. The RUC also cited the second highest key reference service, CPT code 73562 (*Radiologic examination, knee; 3 views*) with a work RVU of 0.18, intraservice time of 4 minutes, and total time of 6 minutes. They noted that, while the survey code has lower intraservice time (3 minutes) and total time (5 minutes) compared with CPT code 73562, the survey code is more complex than the key reference service, thereby supporting a higher work RVU for the survey code (CPT code 70360) of 0.20. We do not agree with the RUC that the work RVU for CPT code 70360 should increase from 0.17 to 0.20. The total time for the CPT code, as recommended by the RUC (5 minutes), is unchanged from the existing total time. Without a corresponding discussion of why the current work RVU is insufficient, disagreed that there should be an increase in the work RVU. Furthermore, although the RUC's recommendation is consistent with the 25th percentile of survey results for the work RVU, the total time from the survey results was 6 minutes, not the RUC-recommended time of 5 minutes. We looked at CPT codes with similar (incorrectly stated as identical in the CY 2020 PFS proposed rule) times to the survey code for a crosswalk, we identified CPT code 73552 (*Radiologic examination, femur; minimum 2 views*), which has a work RVU of 0.18. We believe this is a more appropriate valuation for CPT code 70360 and proposed a work RVU for this CPT code of 0.18.

We proposed the RUC-recommended direct PE inputs for CPT code 70360.

We received public comments on the proposed valuation of the codes in the X-Ray Exam—Neck family. The following is a summary of the comments we received and our responses.

Comment: A commenter noted that CMS' statement that they ''looked at CPT codes with identical times to the survey code for a crosswalk'' and identified 73552. However, the times for the two codes are not, in fact, identical. The intra-service time differs by a full minute which is a key component of a valid crosswalk.

Response: We thank the commenter for bringing this to our attention. We apologize for the confusion and corrected this typo in this final rule to reflect that the times are similar.

Comment: Several commenters disagreed with the proposed work RVUs for CPT code 70360). Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for this procedure. Commenters disagreed with our reference to older work time sources, and noted that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, in this case, were not surveyed, and therefore, were not resource-based. Commenters noted that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC for the services.

Response: We appreciate the commenters' concerns regarding CMS' interpretation of older work time sources and their use in the code valuation process for establishing work RVUs for these services. We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Based on the aforementioned crosswalks, brackets, or references for these codes, which continue to believe

the proposed values better maintains the relative intensity of the codes in the family, and better preserves relativity with the rest of the codes on the PFS

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for the code in the X-Ray Exam—Neck family as proposed.

(31) X-Ray Exam—Spine (CPT Codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120)

CPT codes 72020 (*Radiologic examination spine, single view, specify level*) and 72072 (*Radiologic examination, spine; thoracic, 3 views*) were identified through a screen of CMS/Other Source codes with Medicare utilization greater than 100,000 services annually. The code family was expanded to include 10 additional CPT codes to be reviewed together as a group: CPT code 72040 (*Radiologic examination, spine, cervical; 2 or 3 views*), CPT code 72050 (*Radiologic examination, spine, cervical; 4 or 5 views*), CPT code 72052 (*Radiologic examination, spine cervical; 6 or more views*), CPT code 72070 (*Radiologic examination spine; thoracic, 2 views*), CPT code 72074 (*Radiologic examination, spine; thoracic, minimum of 4 views*), CPT code 72080 (*Radiologic examination, spine; thoracolumbar junction, minimum of 2 views*), CPT code 72100 (*Radiologic examination, spine, lumbosacral; 2 or 3 views*), CPT code 72110 (*Radiologic examination, spine, lumbosacral; minimum of 4 views*), CPT code 72114 (*Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views*), and CPT code 72120 (*Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views*). This family of CPT codes was originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey these codes and the RUC reviewed them again in January 2019.

For the majority of CPT codes in this family, the RUC recommended a work RVU that is slightly different (higher or lower) than the current work RVU. Three CPT codes in this family are maintaining the current work RVU. We proposed the RUC-recommended work RVU for all 12 CPT codes in this family as follows: A work RVU of 0.16 for CPT code 72020, a work RVU of 0.22 for CPT code 72040, a work RVU of 0.27 for CPT code 72050, a work RVU of 0.30 for CPT code 72052, a work RVU of 0.20 for CPT code 72070, a work RVU of 0.23 for CPT code 72072, a work RVU of 0.25 for CPT code 72074, a work RVU of 0.21 for CPT 72080, a work RVU of 0.22 for CPT code 72100, a work RVU of 0.26 for CPT code 72110, a work RVU of 0.30 for CPT code 72114, and a work RVU of 0.22 for CPT code 72120.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the X-Ray Exam—Spine family. The following is a summary of the comments we received and our responses.

Comment: A commenter was supportive of our proposals for the work RVUs and direct PE inputs for the codes in this family.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the X-Ray Exam—Spine family as proposed.

(32) CT-Orbit-Ear-Fossa (CPT Codes 70480, 70481, and 70482)

In October 2017, the RAW requested that AMA staff develop a list of CMS/Other codes with Medicare utilization of 30,000 or more. CPT code 70480 (*Computed tomography (CT), orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material*) was identified. In addition, the code family was expanded to include two related CT codes, CPT code 70481 (*Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material*) and CPT code 70482 (*Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material followed by contrast material(s) and further sections*). In 2018, the RUC recommended this code family be surveyed.

For CPT code 70840, we disagreed with the RUC-recommended work RVU of 1.28 and proposed instead a work RVU of 1.13. We proposed a lower work RVU because 1.13 represents the commensurate 12 percent decrease in work time reflected in survey values. We referenced the work RVUs of CPT codes 72128 (*Computed tomography, chest, spine; without dye*) and 71250 (*Computed tomography, thorax without dye*) both of which have the same intraservice time (that is, 15 minutes) as CPT code 70840 but longer total times (that is, 25 minutes versus 22 minutes). We believe that CPT code 72128 with a work RVU of 1.0 and CPT code 71250 with a work RVU of 1.16 more accurately reflect the relative work values of CPT code 70840.

We also disagreed with the RUC-recommended work RVU of 1.13 for CPT code 70481. Instead, we proposed a work RVU of 1.06 for CPT code 70481. As with CPT code 70840, we proposed a lower work RVU for CPT code 70481 because a work RVU of 1.06 is commensurate with the 23 percent decrease in surveyed total time from 26 to 20 minutes. We believe CPT code 76641 (*Ultrasound, breast, unilateral*) with a work RVU of 0.73 and CPT code 70460 (*Computed Tomography, head or brain, without contrast*) with a work RVU of 1.13 serve as appropriate references for our proposed work RVU for CPT code 70841. Although CPT codes 76641 and 70460 have longer total times at 22 minutes and lower intraservice times at 12 minutes, we believe they better reflect the relative work value of CPT code 70481 with a proposed work RVU of 1.06, total time of 20 minutes, and intraservice time of 13 minutes.

For the third code in the family, CPT code 70482, we proposed the RUC-recommended work RVU of 1.27.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the CT-Orbit-Ear-Fossa family. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for our proposal to accept the RUC-recommended work RVU for CPT code 70482. However, they disagreed with our proposal to lower the work RVUs commensurate with decreases in time for CPT codes 70480 and 70481. Commenters uniformly requested that we reconsider the work RVUs because the work associated with the CPT code 70482 is more anatomically complex than the code we proposed as reference. Additionally, commenters indicated that this particular family of CT codes does not reflect the typical step-up in time and work as is the case for most radiology code families. Commenters noted too that the RUC-recommended values fell at the survey 25th percentile or below as is typical of work valuations.

Response: We thank the commenters for their insights into the services associated with CPT codes 70480, 70481, and 70482. We were persuaded by their comments and will finalize the three codes with the RUC-recommended work RVUs.

Comment: Commenters disagreed with the proposal of the RUC-recommended direct PE inputs for CPT

codes 70480–70482, which would lower CT equipment time by approximately one-third. The commenters stated that based on their experience in actual imaging center practice CT equipment time should be based on the actual, total CT technologist time, rather than the RUC-recommended PE inputs that are not supported by standard operating procedures. Commenters stated that that once the patient is greeted and gowned, he/she will be escorted into the CT room where the technologist will perform the other procedure-related activities such as confirming the exam to be performed against the order, determining the correct exam protocol, etc.

Response: We disagree with the commenters that the RUC-recommended and CMS proposed CT equipment times for the codes in this family are inaccurate. We continue to believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure and are typically available for other patients even when one member of clinical staff may be occupied with a preservice or postservice task related to the procedure. For a more detailed description of this topic, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67639 through 67640).

After consideration of the public comments, we are finalizing the RUC-recommended values for all three codes in the CT-Orbit-Ear-Fossa family: CPT codes 70480 with work RVU 1.28, 70481 with work RVU 1.13, and 70482 with work RVU 1.27. We also are finalizing the RUC-recommended direct PE inputs for all three codes.

(33) CT Spine (CPT Codes 72125, 72126, 72127, 72128, 72129, 72130, 72131, 72132, and 72133)

CPT code 72132 (*Computed tomography, lumbar spine; with contrast material*) was identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. Eight other spine CT codes were identified as part of the family, and they were surveyed and reviewed together at the April 2018 RUC meeting.

We proposed the RUC-recommended work RVU for eight of the nine codes in the family. We proposed a work RVU of 1.22 for CPT code 72126 (*Computed tomography, cervical spine; with contrast material*), a work RVU of 1.27 for CPT code 72127 (*Computed tomography, cervical spine; without contrast material, followed by contrast material(s) and further sections*), a work RVU of 1.00 for CPT code 72128 (*Computed tomography, thoracic spine; without contrast material*), a work RVU of 1.22 for CPT code 72129 (*Computed tomography, thoracic spine; with contrast material*), a work RVU of 1.27 for CPT code 72130 (*Computed tomography, thoracic spine; without contrast material, followed by contrast material(s) and further sections*), a work RVU of 1.00 for CPT code 72131 (*Computed tomography, lumbar spine; without contrast material*), a work RVU of 1.22 for CPT code 72132 (*Computed tomography, lumbar spine; with contrast material*), and a work RVU of 1.27 for CPT code 72133 (*Computed tomography, lumbar spine; without contrast material, followed by contrast material(s) and further sections*).

We disagree with the RUC-recommended work RVU of 1.07 for CPT code 72125 (*Computed tomography, cervical spine; without contrast material*) and we proposed a work RVU of 1.00 to match the other without contrast codes in the family. The cervical spine CT procedure described by CPT code 72125 shares the identical surveyed work time as the thoracic spine CT procedure described by CPT code 72128 and the lumbar spine CT procedure described by CPT code 72131, and we believe that this indicates that these three CPT codes should share the same work RVU of 1.00. Our proposed work RVU would also match the pattern established by the rest of the codes in this family, in which the contrast procedures (CPT codes 72126, 72129, and 72132) share a proposed work RVU of 1.22 and the without/with contrast procedures (CPT codes 72127, 72130, and 72133) share a proposed work RVU of 1.27.

We recognize that the RUC has stated that they believe CPT code 72125 to be a more complex study than CPT codes 72128 and 72131 because the cervical spine is subject to an increased number of injuries and there are a larger number of articulations to evaluate. This was the basis for their recommendation that this code should be valued slightly higher than the other without contrast codes. However, if CPT code 72125 has a more difficult patient population and requires a larger number of articulations to evaluate as compared to CPT codes 72128 and 72131, we do not understand why this was not reflected in the surveyed work times, which were identical for the three procedures. We believe that if the intensity of the procedure were higher due to these additional difficulties, it would be reflected in a longer surveyed work time. In addition, the survey respondents selected a higher work RVU for CPT code 72131 than CPT code 72125 at both the survey 25th percentile (1.20 to 1.18) and survey median values (1.39 to 1.28), which does not suggest that CPT code 72125 should be valued at a higher rate.

We also note that the surveyed intraservice work time for CPT code 72125 is decreasing from 15 minutes to 12 minutes, and we believe that this provides additional support for a slight reduction in the work RVU to match the other without contrast codes in the family. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of prior work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the CT Spine family. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the CMS proposed work RVU of 1.00 for CPT code 72125 and stated that CMS should instead finalize the RUC-recommended work RVU of 1.07. Commenters stated that CPT code 72125 is a more complex service compared to CPT codes 72128 and 72131 because the cervical spine is subject to an increased number of injuries and there are a larger number of articulations to evaluate including the joints at the craniocervical junction, facet and uncovertebral joints.

Response: We disagree with the commenters that CPT code 72125 is a more complex service compared to CPT codes 72128 and 72131. We acknowledged that the RUC had provided this rationale in their recommendations for CPT code 72125, and we cited the data from the survey respondents that led us to believe that this was not the case. We did not receive a response from the commenters

addressing our use of the survey data, and therefore, we continue to believe that CPT code 72125 should not be valued higher than CPT codes 72128 and 72131.

Comment: Several commenters referenced how the codes in this family had been valued during previous reviews, stating that CMS had previously refined the work RVU of CPT codes 72128 and 72131 to 1.00 while finalizing the RUC-recommended work RVU of 1.07 for CPT code 72125. Commenters stated that because CMS reduced the work RVU for these codes but kept the RUC-recommended work RVUs, there was incongruence between their work times in the RUC database and the existing work RVUs. Commenters also stated that CPT codes with the same or similar times can, and should, have varying RVUs; even though the times for these codes are the same, commenters stressed that the intensity of work for CPT code 72125 is higher than CPT codes 72128 or 72131 due to more anatomical complexity in the cervical spine and the risk of injury to the patient.

Response: We appreciate the additional information provided by the commenters regarding the previous review of these codes in an earlier rule cycle. However, since all nine codes in the family were re-surveyed and produced new survey data, we believe that it is more appropriate to base their valuation on the current survey results, as opposed to the historical survey results. We continue to believe that if the intensity of CPT code 72125 were higher than CPT codes 72128 or 72131 due to the additional difficulties mentioned by the commenters, it would be reflected in a longer surveyed work time. We also note again that the survey respondents selected a higher work RVU for CPT code 72131 than CPT code 72125 at both the survey 25th percentile (1.20 to 1.18) and survey median values (1.39 to 1.28), which does not suggest that CPT code 72125 should be valued at a higher rate. We did not receive any comments explaining why the survey respondents valued CPT code 72125 lower than CPT code 72131 yet it should be valued at a higher rate.

In more general terms, we agree with the commenters that CPT codes with the same or similar times can, and should, have varying RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work. We clarify again that we do not treat all components of physician time as having identical intensity. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277). In the specific case of CPT code 72125, we believe that it should share the same work RVU of 1.00 with CPT codes 72128 and 72131 not solely because these three codes share the same work times, but also because it matches the pattern established by the rest of the codes in this family, in which the contrast procedures (CPT codes 72126, 72129, and 72132) share a proposed work RVU of 1.22 and the without/with contrast procedures (CPT codes 72127, 72130, and 72133) share a proposed work RVU of 1.27.

Comment: Several commenters disagreed with the proposal of the RUC-recommended direct PE inputs for CPT codes 72125–72133, which would lower CT equipment time by approximately one-third. The commenters stated that, based on their experience in actual imaging center practice, CT equipment time should be based on the actual, total CT technologist time, rather than the RUC-recommended PE inputs that are not supported by standard operating procedures. Commenters stated that that once the patient is greeted and gowned, he/she will be escorted into the CT room where the technologist will perform the other procedure-related activities such as confirming the exam to be performed against the order, determining the correct exam protocol, etc.

Response: We disagree with the commenters that the RUC-recommended and CMS proposed CT equipment times for the codes in this family were inaccurate. We continue to believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure and are typically available for other patients even when one member of clinical staff may be occupied with a preservice or postservice task related to the procedure. For a more detailed description of this topic, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67639 through 67640).

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the CT Spine family as proposed.

(34) X-Ray Exam—Pelvis (CPT Codes 72170 and 72190)

CPT code 72190 (*Radiologic examination, pelvis; complete, minimum of 3 views*) was identified as potentially misvalued through a screen of CMS/Other codes with Medicare utilization of 30,000 or more annually. CPT code 72170 (*Radiologic examination, pelvis; 1 or 2 views*) was added as part of the family. The RUC originally reviewed these two codes after specialty societies employed a crosswalk methodology to value work and PE. However, after we expressed concern about the use of this approach, the specialty society agreed to survey the codes and the RUC reviewed them again at the meeting in January 2019.

The RUC recommended a work RVU of 0.17 for CPT code 72170, which maintains the current value. For CPT code 72190, the RUC recommended a work RVU of 0.25, which is slightly higher than the current value (work RVU of 0.21). We proposed the RUC-recommended work RVUs for these two codes in this family.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

Comment: A commenter was supportive of our proposals for the work RVUs and direct PE inputs for the codes in this family.

Response: We appreciate the support for our proposals from the commenter. After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the X-Ray Exam—Pelvis family as proposed.

(35) X-Ray Exam—Sacrum (CPT Codes 72200, 72202, and 72220)

CPT code 72220 (*Radiologic examination, sacrum and coccyx, minimum of 2 views*) was identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 annually. CPT codes 72200 (*Radiologic examination, sacroiliac joints; less than 3 views*) and 72202 (*Radiologic examination, sacroiliac joints; 3 or more views*) were also included for review as part of the same family of codes. These three codes were originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey these codes and the RUC reviewed them again in January 2019.

For CPT code 72200, we disagreed with the RUC recommended work RVU of 0.20, and proposed a work RVU of 0.17, which maintains the current value. We were concerned that the large variation in specialty societies' survey times is indicative of differences in patient population, practice workflow, or even possibly some ambiguity associated with the survey vignette. Furthermore, we did not agree that there is sufficient justification for an increase in work RVU for this service. To support their recommendation, the RUC compared the survey code to the key reference service, CPT code 73522 (*Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views*), with a work RVU of 0.29, 5 minutes of intraservice time and 7 minutes of total time. The intraservice and total times for the key reference service are 1 minute higher than the survey code (4 minutes intraservice time, 6 minutes total time for CPT code 72200) and the survey code is less intense, according to the RUC, thereby supporting a slightly lower work RVU of 0.20 for CPT code 72200. The RUC's second key reference service is CPT code 73562 (*Radiologic examination, knee; 3 views*), with 4 minutes of intraservice time, 6 minutes of total time, and a work RVU of 0.18. The RUC noted that this second key reference service is less intense to furnish than the survey code, which justifies a slightly lower work RVU despite identical intraservice time (4 minutes) and total time (6 minutes). The RUC further supported their recommendation with a bracket to CPT code 93042 (*Rhythm ECG, 1–3 leads; interpretation and report only*), which has a work RVU of 0.15, and CPT code 70355 (*Orthopantogram (e.g., panoramic x-ray)*), which has a work RVU of 0.20 (which is identical to the RUC-recommended work RVU for CPT code 72200 but has one additional minute of intraservice time). Although the RUC-recommended work RVU of 0.20 is consistent with the work RVU estimated by the TTR and reflects the 25th percentile of survey results, we do not agree that there is sufficient justification for an increase in work RVU for this service. We also note that the 25th percentile of the survey results work RVU of 0.20 proposed by the RUC is based on the overall survey total time, which is 8 minutes, rather than the RUC-recommended 6 minutes. We found no corresponding explanation for the variability in survey times, leading us to question why there should be an increase in work RVU from the current value. Therefore, we proposed to maintain the current work RVU of 0.17 for CPT code 72200.

For CPT code 72202, we disagreed with the RUC-recommended work RVU of 0.26, and proposed a work RVU of 0.23 based on our increment methodology. Our proposed value is supported by a bracket to CPT code 73521 (*Radiologic examination, hips, bilateral, with pelvis when performed; 2 views*), which has a work RVU of 0.22 and similar time values, and CPT code 74021 (*Radiologic examination, abdomen; 3 or more views*), which has a work RVU 0.27, and identical time values, to CPT code 72202. Although we disagreed with the RUC-recommended work RVU of 0.20 for CPT code 72200 (the prior code in this family), based on RUC survey results and the time resources involved in furnishing CPT codes 72200 and 72202, we agreed that the relative difference in work RVUs between CPT codes 72200 and 72202 is equivalent to the RUC-recommended incremental difference of 0.06 additional work RVUs. The RUC supported their recommendation with two key reference services. The first is CPT code 73522 (*Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views*) with 5 minutes intraservice time, 7 minutes total time, and a work RVU of 0.29. They noted that this code has an additional minute for intraservice and total time compared with the survey code, reflecting the additional views associated with evaluating bilateral hip joints. The RUC's second key reference service is CPT code 73562 (*Radiologic examination, knee; 3 views*) with 4 minutes intraservice time, 6 minutes total time, and a work RVU of 0.18. The RUC notes that the survey code has the same times but requires more intensity and includes an additional view compared with the reference service, which the RUC notes justifies a higher work RVU for the survey code.

We disagreed with the RUC's recommended work RVU for CPT code 72202. Given that there is no change in the total time required to furnish the service and there is no corresponding description of an increase in the intensity of the work relative to the existing value, we do not believe an increase in the work RVU for this service is warranted. Therefore, based on those concerns and our incremental methodology, supported by a bracket to CPT codes 73521 and 74021, we proposed a work RVU of 0.23 for CPT code 72202.

For CPT code 72220 we disagreed with the RUC-recommended work RVU 0.20 and proposed to maintain the current work RVU of 0.17. We note that there is no change in the total time required to furnish the service. We also note that a work RUC-recommended RVU of 0.20 for CPT code 72220 would place it near the maximum work RVU for CPT codes with identical intraservice time (3 minutes) and total time (5 minutes). The RUC's key reference service from the survey results is CPT code 73522 (*Radiologic examination, hips, bilateral, with pelvis when performed, 2–4 views*), has a work RVU of 0.29, 5 minutes intraservice time, and 7 minutes total time. The RUC noted that their recommended work RVU for CPT code 72220 has a lower value than the top key reference code (CPT code 73522) because of the shorter time and lower intensity involved in furnishing the survey code. The RUC's second highest key reference service, CPT code 73562 (*Radiologic examination, knee; 3 views*) has a work RVU of 0.18 with 4 minutes of intraservice time and 6 minutes of total time. The RUC noted that this second key reference service has a lower work RVU than the survey code despite having a slightly higher intraservice time and total time because it involves an X-ray of just one knee.

We disagree with the RUC's recommended increase in the work RVU for CPT code 72220 from 0.17 to 0.20. We note that there is no change in the total time required to furnish the service and that the RUC-recommended work RVU would place it near the maximum work RVU for CPT codes with identical intraservice time (3 minutes) and total time (5 minutes). Therefore, based on those concerns we proposed to maintain the current work RVU of 0.17 for CPT code 72220.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the X-Ray Exam—Sacrum family. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they supported the proposal of the RUC-recommended direct PE inputs for the code in the family.

Response: We appreciate the support for our proposal for the direct PE inputs from the commenters.

Comment: Several commenters disagreed with the proposed work RVUs for CPT codes 72200 and 72220. Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for these procedures. Commenters disagreed with our reference to older work time sources, and noted that their use led to the proposal of work RVUs based on flawed

assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, in this case, were not surveyed, and therefore, were not resource-based. Commenters noted that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC for the services.

Response: We appreciate the commenters' concerns regarding CMS' interpretation of older work time sources and their use in the code valuation process for establishing work RVUs for these services. We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Our proposal to maintain the current work RVUs for CPT codes 72200 (a work RVU of 0.17) and 72220 (a work RVU of 0.17) and a work RVU of 0.23 for CPT code 72202 is supported by the aforementioned bracket to CPT codes 73521 and 74021. We continue to believe the proposed values better maintains the relative intensity of the codes in the family, and better preserves relativity with the rest of the codes on the PFS.

Comment: A commenter stated that CMS' note in the proposed rule regarding the reduction in time is misleading. A commenter disagreed with the CMS proposed work RVU for CPT code 72202. One commenter stated that CMS should instead finalize the RUC-recommended work RVU for this procedure, stating that the incremental methodology used in valuing these services was flawed; the commenter did not agree that it was appropriate to reduce the work RVU for CPT code 72202 from the value proposed by the RUC, while also recalibrating the work relative to the RUC's recommended difference in work between this code and CPT code 72200. A commenter noted that it is imperative to employ RUC survey data to value this service, and that using an incremental approach in lieu of survey data, strong crosswalks, and input from the practitioners providing these services was unjustified.

Response: We apologize for the confusion noted by commenters who stated that the reduction in time for CPT code 72200 was misleading. In this final rule we have clarified our note on the reductions in time in the discussion above on this code. We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Thus, we applied the use of an incremental difference between CPT codes 72202 and 72200 to develop the proposed work RVU for CPT code. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the X-Ray Exam—Sacrum family as proposed.

(36) X-Ray Exam—Clavicle-Shoulder (CPT Codes 73000, 73010, 73020, 73030, and 73050)

CPT code 73030 (*Radiologic examination, shoulder; complete, minimum of 2 views*) was identified as potentially misvalued through a screen of services with more than 100,000 utilization annually. CPT codes 73000 (*Radiologic examination; clavicle, complete*), 73010 (*Radiologic examination; scapula, complete*), 73020 (*Radiologic examination, shoulder; 1 view*), and 73050 (*Radiologic examination, acromioclavicular joints, bilateral, with or without weighted distraction*) were included for review as part of the same family. We proposed the RUC-recommended work RVUs for all five codes in this family. We proposed a work RVU of 0.16 for CPT code 73000, a work RVU of 0.17 for CPT code 73010, a work RVU of 0.15 for CPT code 73020, a work RVU of 0.18 for CPT code 73030, and a work RVU of 0.18 for CPT code 73050.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

Comment: A commenter was supportive of our proposals for the work RVUs and direct PE inputs for the codes in this family.

Response: We appreciate the support for our proposals from the commenter. After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the X-Ray Exam—Clavicle-Shoulder family as proposed.

(37) CT Lower Extremity (CPT Codes 73700, 73701, and 73702)

CPT code 73701 (*Computed tomography, lower extremity; with contrast material(s)*) was identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. Two other lower extremity CT codes were identified as part of the family, and they were surveyed and reviewed together at the April 2018 RUC meeting.

We proposed the RUC-recommended work RVU for all three codes in this family. We proposed a work RVU of 1.00 for CPT code 73700 (*Computed tomography, lower extremity; without contrast material*), a work RVU of 1.16 for CPT code 73701 (*Computed tomography, lower extremity; with contrast material(s)*), and a work RVU of 1.22 for CPT code 73702 (*Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further sections*).

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the CT Lower Extremity family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposal of the RUC-recommended work RVUs for the codes in the family.

Response: We appreciate the support for our proposals from the commenter.

Comment: Several commenters disagreed with the proposal of the RUC-recommended direct PE inputs for CPT

codes 73700–73702, which would lower CT equipment time by approximately one-third. The commenters stated that, based on their experience in actual imaging center practice, CT equipment time should be based on the actual, total CT technologist time, rather than the RUC-recommended PE inputs that are not supported by standard operating procedures. Commenters stated that that once the patient is greeted and gowned, he/she will be escorted into the CT room where the technologist will perform the other procedure-related activities such as confirming the exam to be performed against the order, determining the correct exam protocol, etc.

Response: We disagree with the commenters that the RUC-recommended and CMS proposed CT equipment times for the codes in this family are inaccurate. We continue to believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure and are typically available for other patients even when one member of clinical staff may be occupied with a preservice or postservice task related to the procedure. For a more detailed description of this topic, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67639 through 67640).

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the CT Lower Extremity family as proposed.

(38) X-Ray Elbow-Forearm (CPT Codes 73070, 73080, and 73090)

CPT codes 73070 (*Radiologic examination, elbow; 2 views*) and 73090 (*Radiologic examination; forearm, 2 views*) were identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73080 (*Radiologic examination, elbow; complete, minimum of 3 views*) was included for review as part of the same code family. All three CPT codes in this family were originally valued by the specialty societies using a crosswalk methodology approved by the RUC research committee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey the codes and the RUC reviewed them again at the meeting in January 2019. We proposed the RUC-recommended work RVU for all three codes in this family. We proposed a work RVU of 0.16 for CPT code 73070, a work RVU of 0.17 for CPT code 73080, and a work RVU of 0.16 for CPT code 73090.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

Comment: A commenter was supportive of our proposals for the work RVUs and direct PE inputs for the codes in this family.

Response: We appreciate the support for our proposals from the commenter. After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the X-Ray Elbow-Forearm family as proposed.

(39) X-Ray Heel (CPT Code 73650)

CPT code 73650 (*Radiologic examination; calcaneous, minimum of 2 views*) was identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73650 was originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey the code and the RUC reviewed it again in January 2019. For CPT code 73650, we proposed the RUC-recommended work RVU of 0.16.

We proposed the RUC-recommended direct PE inputs for CPT code 73650.

Comment: A commenter was supportive of our proposals for the work RVUs and direct PE inputs for the code in this family.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the code in the X-Ray Heel family as proposed.

(40) X-Ray Toe (CPT Code 73660)

CPT code 73660 (*Radiologic examination; toe(s), minimum of 2 views*) was identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73660 was originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey the code and the RUC reviewed it again in January 2019. We proposed the RUC-recommended work RVU of 0.13 for CPT code 73660.

We proposed the RUC-recommended direct PE inputs for CPT code 73660.

Comment: A commenter was supportive of our proposals for the work RVUs and direct PE inputs for the code in this family.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the code in the X-Ray Toe family as proposed.

(41) Upper Gastrointestinal Tract Imaging (CPT Codes 74210, 74220, 74230, 74221, 74240, 74246, and 74248)

These services were identified through a list of list of CMS/Other codes with Medicare utilization of 30,000 or more. The CPT Editorial Panel subsequently revised this code set in order to conform to other families of radiologic examinations.

We proposed the RUC-recommended work RVUs of 0.59 for CPT code 74210 (*Radiologic examination, pharynx and/or cervical esophagus, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*), 0.60 for CPT code 74220 (*Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study*), 0.70 for CPT code 74221 (*Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high-density barium and effervescent agent) study*), 0.53 for CPT code 74230 (*Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*), 0.80 for CPT code 74240 (*Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study*) 0.90 for CPT code 74246 (*Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high-density barium and effervescent agent) study, including glucagon, when administered*), and 0.70 for CPT code 74248 (*Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; with small intestine follow-through study, including multiple serial images (List separately in addition to code for primary procedure)*). We are also proposing the reaffirmed work RVU of 0.59 for CPT code 74210 (*Radiologic examination, pharynx and/or cervical esophagus,*

including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study) and the reaffirmed work RVU of 0.53 for CPT code 74230 (*Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*).

For the direct PE clinical labor input CA021 ''Perform procedure/service—NOT directly related to physician work time,'' we noted that no rationale was given for the RUC-recommended times for these codes, and we requested comment on the appropriateness of the RUC-recommended clinical labor times for this activity of 13 minutes, 13 minutes, 15 minutes, 15 minutes, 19 minutes, 22 minutes, and 15 minutes for CPT codes 74210, 74220, 74221, 74230, 74240, and 74246, respectively. In addition, for CPT code 74230, we proposed to refine the clinical labor times for the ''Prepare room, equipment and supplies'' (CA013) and ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity codes to the standard values of 2 minutes each, as well as to refine the equipment times to reflect these changes in clinical labor.

We received public comments on the proposed valuation of the codes in the Upper Gastrointestinal Tract Imaging family. The following is a summary of the comments we received and our responses.

Comment: A commenter supported our proposal to use the RUC-recommended work RVUs for these codes.

Response: We appreciate the support for our proposals from the commenter.

Comment: A commenter stated that, contrary to our statement that no rationale was provided for the times recommended for the ''perform procedure/service—NOT directly related to physician work time'' (CA021) clinical labor activity, the RUC had included detailed information on the RUC-recommended clinical labor in the PE SOR, and the commenter reiterated the rationale.

Response: We thank the commenter for the clarification.

Comment: A commenter disagreed with our refinements to the RUC-recommended minutes for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity. This commenter stated patients require extra time for positioning because by CMS' own policy rules these patients need two diagnoses to qualify for the exam, the most common being prior cerebral infarct and pneumonia. The patients are elderly, debilitated, and have multiple comorbidities. They are being positioned upright between a table and fluoroscopy tube with minimal allowance for deviation because the field of view (their oropharynx and larynx) are a small target.

A commenter disagreed with our proposed refinement to the number of minutes allocated to the ''Prepare room, equipment and supplies'' (CA013) activity, stating that this exam's requirements exceed a normal radiographic exam. The commenter stated that multiple consistencies of barium must be prepared, including thin liquid, nectar thick liquid, honey-thick liquid, purees, mixed solids, and solids and that the varying barium consistencies are delivered by teaspoon, straw, and cup. The commenter stated that all of these items must be prepared prior to beginning the exam.

Response: We appreciate the additional information provided by commenters regarding these clinical labor activities. Based on the information provided by the commenters, we are not finalizing our proposed refinements to the CA013 and CA016 clinical labor activities, and we are instead finalizing the RUC-recommended times.

After consideration of the public comments, we are finalizing as proposed the RUC-recommended work RVUs, as well as the RUC-recommended direct PE inputs.

(42) Lower Gastrointestinal Tract Imaging (CPT Codes 74250, 74251, 74270, and 74280)

These services were identified through a list of list of CMS/Other codes with Medicare utilization of 30,000 or more. We proposed the RUC-recommended work RVUs of 0.81 for CPT code 74250 (*Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; single-contrast (e.g., barium) study*), 1.17 for CPT code 74251 (*Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; double-contrast (e.g., high-density barium and air via enteroclysis tube) study, including glucagon, when administered*), 1.04 for 74270 (*Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study*), and 1.26 for CPT code 74280 (*Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high density barium and air) study, including glucagon, when administered*).

For the direct PE clinical labor input CA021 ''Perform procedure/service—NOT directly related to physician work time,'' we noted that no rationale was given for the recommended times for these codes, and we requested comment on the appropriateness of the RUC-recommended clinical labor times for this activity of 19 minutes, 30 minutes, 25 minutes, and 36 minutes for CPT codes 74250, 74251, 74270, and 74280, respectively. In addition, we proposed to refine the equipment time for the room, radiographic-fluoroscopic (EL014) for CPT code 74250 to conform to our established standard for highly technical equipment and to match the rest of the codes in the family.

We received public comments on the proposed valuation of the codes in the Lower Gastrointestinal Tract Imaging family. The following is a summary of the comments we received and our responses.

Comment: A commenter supported our proposal to use the RUC-recommended work RVUs for these codes.

Response: We appreciate the support for our proposals from the commenter.

Comment: A commenter stated that, contrary to our statement that no rationale was provided for the times recommended for the ''perform procedure/service—NOT directly related to physician work time'' (CA021) clinical labor activity, the RUC had included detailed information on the RUC-recommended clinical labor in the PE SOR, and the commenter reiterated the rationale.

Response: We thank the commenter for the clarification. We are finalizing the RUC-recommended times as proposed for this clinical labor activity.

After consideration of the public comments, we are finalizing as proposed the RUC-recommended work RVUs, as well as our proposed direct PE refinements.

(43) Urography (CPT Code 74425)

The service described by CPT code 74425 (*Urography, antegrade (pyelostogram, nephrostogram, loopogram), radiological supervision and interpretation*) was combined with services describing genitourinary catheter procedures by the CPT Editorial Panel in CY 2016, resulting in CPT codes 50431 (*Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance*

(e.g., ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; existing access) and 50432 (*Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation*). CPT code 74425 was not deleted at the time, but the RUC agreed with the specialty societies that 2 years of Medicare claims data should be available for analysis before the code was resurveyed for valuation to allow for any changes in the characteristics and process involved in furnishing the service separately from the genitourinary catheter procedures. The specialty society surveyed CPT code 74425 and reviewed the results with the RUC in October 2018.

The results of the specialty society surveys indicated a large increase in the amount of time required to furnish the service and, correspondingly, to the work RVU. The total time for CPT code 74425 based on the survey results was 34 minutes, an increase of 25 minutes over the current total time of 9 minutes. In reviewing the survey results, the RUC revised the total time for this CPT code to 24 minutes, with a recommended work RVU of 0.51. The reason for the large increase in time, according to the RUC, is a change in the typical patient profile in which the typical patient is one with an ileal conduit through which nephrostomy tubes have been placed for post-operative obstruction. Based on the described change in patient population and increased time required to furnish the service, we proposed the RUC-recommended work RVU of 0.51 for CPT code 74425.

We proposed the RUC-recommended direct PE inputs for CPT code 74425.

We received public comments on the proposed valuation of the codes in the Urography family. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they supported our proposals for the work RVUs and direct PE inputs for the code in this family

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the code in the Urography family as proposed.

(44) Abdominal Aortography (CPT Codes 75625 and 75630)

In October 2017, the RAW requested that AMA staff compile a list of CMS/Other codes with Medicare utilization of 30,000 or more. In January 2018, the RUC recommended to survey these services for the October 2018 RUC meeting. Subsequently, the specialty society surveyed these codes.

We disagree with the RUC-recommended work RVU of 1.75 for CPT code 75625 (*Aortography, abdominal, by serialography, radiological supervision and interpretation*). In reviewing CPT code 75625, we note that the key reference service, CPT Code 75710 (*Angiography, extremity, unilateral, radiological supervision and interpretation*), has 10 additional minutes of intraservice time, 10 additional minutes of total time and the same work RVU, which would indicate the RUC-recommended work RVU of 1.75 appears to be overvalued. When we compared the intraservice time ratio between the RUC-recommended time of 30 minutes and the reference code intraservice time of 40 minutes we found a ratio of 25 percent. 25 percent of the reference code work RVU of 1.75 equals a work RVU of 1.31. When we compared the total service time ratio between the RUC-recommended time of 60 minutes and the reference code total service time of 70 minutes we found a ratio of 14 percent. 14 percent of the reference code work RVU of 1.75 equals a work RVU of 1.51. Therefore, we believe an accurate value would lie between 1.31 and 1.52 RVUs. In looking for a comparative code, we have identified CPT code 38222. CPT Code 38222 is a recently reviewed CPT code with the identical intraservice and total times. As a result, we believe that it is more accurate to propose a work RVU of 1.44 based on a crosswalk to CPT code 38222.

In case of CPT code 75630 (*Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation*), we proposed the RUC-recommended value of 2.00 RVUs.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Abdominal Aortography family. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to value CPT code 75630 with the RUC-recommended work RVU.

Response: We appreciate the support for our proposals from the commenters.

Comment: A few commenters stated that our proposed value for CPT code 75625 is invalid, as it relies on a reference to the current value, and the crosswalk or methodology used in the original valuation of this service is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work.

Response: We believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: A commenter stated that CPT code 38222 provides a poor crosswalk to support our proposed value for CPT code 75625 because it is performed by physicians from a different specialty, it does not involve imaging and exposure to radiation, it does not require intra-arterial access or monitoring of hemodynamic parameters, and it is a much lower risk procedure.

Response: Our determination that the RUC's recommended value somewhat overstates the inherent work is based in part on an analysis of all codes of similar physician time values; we believe the survey data validates an increase in work, but this analysis of all codes of similar times indicates that the increase should not be of the magnitude recommended by the RUC. We note that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another, and that codes do not need to share the same specialty. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. After consideration of the public comments, we are finalizing our proposed work RVUs and direct PE inputs for these codes.

(45) Angiography (CPT Codes 75726 and 75774)

We proposed the RUC-recommend work RVU for both codes in this family. We proposed a work RVU of 2.05 for CPT code 75726 (*Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation*), a work RVU of 1.01 for CPT code 75774 (*Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (List separately in addition to code for primary procedure*).

We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Angiography family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposal of the RUC-recommended work RVUs for the codes in the family.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Angiography family as proposed.

(46) X-Ray Exam Specimen (CPT Code 76098)

CPT code 76098 (*Radiological examination, surgical specimen*) was reviewed by the RUC based on a request from the American College of Radiology (ACR) to determine whether CPT code 76098 was undervalued because of the assumption that the service is typically furnished concurrently with a placement of localization device service (CPT codes 19281 (*Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance*), 19282 (*Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including mammographic guidance (List separately in addition to code for primary procedure*), 19283 (*Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance*), 19284 (*Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including stereotactic guidance (List separately in addition to code for primary procedure*)) 19285 (*Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including ultrasound guidance*), 19286 (*Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including ultrasound guidance (List separately in addition to code for primary procedure*), 19287 (*Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance*), and 19288 (*Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure))* each representing a different imaging modality). In a letter to the RUC, ACR expressed concern about the appropriateness of a codes valuation process in which physician time and intensity for a code are reduced to account for overlap with codes that are furnished to a patient on the same day. During the April 2018 RUC meeting, the specialty societies requested a work RVU of 0.40 for CPT code 76098, with intraservice time of 5 minutes and total time of 15 minutes. Currently, this service has a work RVU of 0.16, with 5 minutes of total time and no available intraservice time. In April 2018, the RUC and the specialty society agreed that additional analysis of the data was warranted in consideration of the relatively large change in survey time and work RVU for this service. The RUC agreed to review CPT code 76098 again in October 2018.

The RUC recommended a work RVU of 0.31 for CPT code 76098, based on the October 2018 meeting, which represents an increase over the current value (0.16), but a decrease relative to the specialty society's original request of 0.40. The intraservice time for this CPT code is 5 minutes, and the total time is 11 minutes. Based on the parameters we typically use to review and evaluate RUC recommendations, which rely heavily on survey data, we agree that a work RVU of 0.31 for a CPT code with 5 minutes intraservice and 11 minutes total time is consistent with other CPT codes with similar times and levels of intensity. We proposed the RUC-recommended work RVU of 0.31 for CPT code 76098.

We share the ACR's interest in establishing or clarifying parameters that indicate when CPT codes that are furnished concurrently by the same provider should be valued to account for the overlap in physician work time and intensity, and even PE. We are broadly interested in stakeholder feedback and suggestions about what those parameters might be and whether or how they should affect code valuation.

We proposed the RUC-recommended direct PE inputs for CPT code 76098.

We received public comments on the proposed valuation of the codes in the X-Ray Exam Specimen family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated appreciation that CMS proposed the RUC-recommended value for CPT code 76098, but wanted to clarify some of the statements in the proposed rule regarding how the code came up for review and their concerns regarding the billed together data. They noted that CPT code 76098 was reviewed by the RUC in April 2018 as part of the CMS/Other utilization >30,000 screen. At that time, RUC members questioned whether 76098 is typically performed with another code on the same patient, same date of service, and by the same provider. Billed together data showed that no single other code was typically performed with CPT code 76098, but if multiple codes (in this case all CPT codes representing placement of needle localization device by any imaging modality) were combined, then the billed together threshold was met. A commenter expressed concern about whether or not it is appropriate to combine multiple similar codes when determining billed together status. The ACR noted that adding individual billed together rates will result in double counting when three or more of those codes are billed together, rendering the data inaccurate unless this overlap is accounted for. Additionally, the ACR expressed concern that this method of determining billed together status reflects a change in RUC procedure and should be validated through the Research Subcommittee before establishing precedent. As further noted by the commenter, since this was a complex, multi-code issue, the RUC decided to revisit this issue at the October 2018 RUC meeting where AMA staff could present their research on this matter. In October 2018, the RUC agreed that CPT code 76098 is typically performed with one type of needle localization on the same day (any of CPT codes 19281–19288), and 4 minutes of pre-service time was removed from the survey time to account for overlap in work.

Response: We appreciate the support for our proposals from the commenter, and the additional information to clarify

how CPT code 76098 came up for review and noting their concerns regarding the billed together data.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the code in the X-Ray Exam Specimen family as proposed.

(47) 3D Rendering (CPT Code 76376)

CPT code 76376 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. It was surveyed and reviewed at the April 2018 RUC meeting.

We proposed the RUC-recommended work RVU of 0.20 for CPT code 76376. We are also proposing the RUC-recommended direct PE inputs for CPT code 76376.

We received public comments on the proposed valuation of the codes in the 3D Rendering family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposal of the RUC-recommended work RVU for CPT code 76376.

Response: We appreciate the support for our proposal from the commenter.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT code 76376 as proposed.

(48) Ultrasound Exam—Chest (CPT Code 76604)

CPT code 76604 (*Ultrasound, chest (includes mediastinum), real time with image documentation*) was identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. It was surveyed and reviewed for the April 2018 RUC meeting.

We proposed the RUC-recommended work RVU of 0.59 for CPT code 76604. We are also proposing the RUC-recommended direct PE inputs for CPT code 76604.

We received public comments on the proposed valuation of the codes in the Ultrasound Exam—Chest family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposal of the RUC-recommended work RVU for CPT code 76604.

Response: We appreciate the support for our proposal from the commenter.

Comment: Several commenters disagreed with the RUC-recommended and CMS proposed replacement of the general ultrasound room (EL015) with a portable ultrasound unit (EQ250) for CPT code 76604. The commenters stated that their members reported using console-based ultrasound systems, which reflect a higher cost than portable ultrasound units, and stated that the direct PE inputs for CPT code 76604 should accurately reflect the cost of equipment being used by radiologic practices and freestanding imaging centers. Commenters stated that they only uses console-based ultrasound systems because of their greater processing power, advanced features, better image quality, and suitability for a wider range of clinical scenarios including obstetrics, breast, vascular, abdominal, and chest.

Response: While we agree with the commenters that the direct PE inputs for CPT code 76604 should accurately reflect equipment usage, we disagree that the use of the ultrasound room would be typical for this procedure. We agree with the RUC recommendations that the practice patterns for CPT code 76604 have changed over time, and that it is no longer typical for patients to require the use of a full ultrasound room for this examination given the widespread availability of highly quality portable ultrasound equipment. We believe that the typical patient would be treated using these portal ultrasounds for their chest examination.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT code 76604 as proposed.

(49) X-Ray Exam—Bone (CPT Codes 77073, 77074, 77075, 77076, and 77077)

CPT codes 77073 (*Bone length studies (orthoroentgenogram, scanogram)*), 77075 (*Radiologic examination, osseous survey; complete (axial and appendicular skeleton)*), and 77077 (*Joint survey, single view, 2 or more joints*) were identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. CPT codes 77074 (*Radiologic examination, osseous survey; limited (e.g., for metastases)*) and 77076 (*Radiologic examination, osseous survey, infant*) were reviewed as part of the same family.

We proposed the RUC-recommended work RVU for all five CPT codes in this family. We proposed a work RVU of 0.26 for CPT code 77073, a work RVU of 0.44 for CPT code 77074, a work RVU of 0.55 for CPT code 77075, a work RVU of 0.70 for CPT code 77076, and a work RVU of 0.33 for CPT code 77077.

We proposed the RUC-recommended direct PE inputs for all codes in the family.

Comment: A commenter was supportive of our proposals for the work RVUs and direct PE inputs for the codes in this family.

Response: We appreciate the support for our proposals from the commenter. After consideration of the public comments, we are finalizing the work RVUs and direct PE for the codes in the X-Ray Exam—Bone family as proposed.

(50) SPECT–CT Procedures (CPT Codes 78800, 78801, 78802, 78803, 78804, 78830, 78831, 78832, and 78835)

The CPT Editorial Panel revised five codes, created four new codes and deleted nine codes to better differentiate between planar radiopharmaceutical localization procedures and SPECT, SPECT–CT and multiple area or multiple day radiopharmaceutical localization/distribution procedures.

For CPT code 78800 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar limited single area (e.g., head, neck, chest pelvis), single day of imaging*), we disagree with the RUC recommendation to assign a work RVU of 0.70 based on the survey 25th percentile to this code, because we believe that it is inconsistent with the RUC-recommended reduction in physician time. We proposed a work RVU of 0.64 based on the following total time ratio: The RUC-recommended 27 minutes divided by the current 28 minutes multiplied by the current work RVU of 0.66, which results in a work RVU of 0.64. We note that this value is bracketed by the work RVUs of CPT code 93287 (*Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system*), with a work RVU of 0.45, and CPT code 94617 (*Exercise test for bronchospasm, including pre- and post-spirometry, electrocardiographic recording(s), and pulse oximetry*), with a work RVU of 0.70. Both of these supporting crosswalks have intraservice time values

of 10 minutes, and they have similar total time values.

For CPT code 78801 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, 2 or more areas (e.g., abdomen and pelvis, head and chest), 1 or more days of imaging or single area imaging over 2 or more days*), we disagree with the RUC recommendation to maintain the current work RVU of 0.79 despite a 22-minute reduction in intraservice time. We believe a reduction from the current value is warranted given the recommended reduction in physician time, and also to be consistent with other services of similar time values. We proposed a work RVU of 0.73 based on the RUC-recommended incremental relationship between this code and CPT code 78800 (a difference of 0.09 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 0.73, we note that it falls between the work RVUs of CPT code 94617 (*Exercise test for bronchospasm, including pre- and post-spirometry, electrocardiographic recording(s), and pulse oximetry*) with a work RVU of 0.70, and CPT code 93280 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead pacemaker system*) with a work RVU of 0.77.

For CPT code 78802 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, whole body, single day of imaging*), we disagree with the RUC recommendation to maintain the current work RVU of 0.86, as we believe that it is inconsistent with a reduction in time values, and because we do not agree that a work RVU that is among the highest of other services of similar intraservice time values is appropriate. We proposed a work RVU of 0.80 based on the RUC-recommended incremental relationship between this code and CPT code 78800 (a difference of 0.16 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 0.80, we note that it falls between the work RVUs of CPT code 92520 (*Laryngeal function studies (i.e., aerodynamic testing and acoustic testing)*) with a work RVU of 0.75, and CPT code 93282 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system*) with a work RVU of 0.85.

For CPT code 78804 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, whole body, requiring 2 or more days of imaging*), we disagree with the RUC recommendation to maintain the current work RVU of 1.07, as we believe that it is inconsistent with a reduction in time values, and because this work RVU appears to be valued highly relative to other services of similar time values. We proposed a work RVU of 1.01 based on the RUC-recommended incremental relationship between this code and CPT code 78800 (a difference of 0.37 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 1.01, we reference CPT code 91111 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report*), which has a work RVU of 1.00 and similar physician time values.

For CPT code 78803 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT), single area (e.g., head, neck, chest pelvis), single day of imaging*), we disagree with the RUC recommendation to increase the work RVU to 1.20 based on the survey 25th percentile to this code, because we believe that it is inconsistent with the RUC-recommended reduction in physician time. We proposed to maintain the current work RVU of 1.09. We support this value with a reference to CPT code 78266 (*Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel and colon transit, multiple days*), which has a work RVU of 1.08, and similar time values.

For CPT code 78830 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (e.g., head, neck, chest or pelvis), single day of imaging*), we disagree with the RUC recommendation to assign a work RVU of 1.60 based on the survey 25th percentile to this code, as this would value this code more highly than services of similar time values. To maintain relativity among services in this family, we proposed a work RVU of 1.49 for CPT code 78830 based on the RUC-recommended incremental relationship between CPT code 78830 and CPT code 78803 (a difference of 0.40 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 1.49, we note that it is bracketed by the work RVUs of CPT codes 72195 (*Magnetic resonance (e.g., proton) imaging, pelvis; without contrast material(s)*) with a work RVU of 1.46, and 95861 (*Needle electromyography; 2 extremities with or without related paraspinal areas*) with a work RVU of 1.54. The physician time values of these services bracket those recommended for CPT code 778X0.

For CPT code 78831 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT), minimum 2 areas (e.g., pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days*), we disagree with the RUC recommendation to assign a work RVU of 1.93 based on the survey 50th percentile to this code, as this would value this code more highly than services of similar time values. To maintain relativity among services in this family, we proposed a work RVU of 1.82 based on the RUC-recommended incremental relationship between this code and CPT code 78803 (a difference of 0.73 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 1.82, we note that it is bracketed by the work RVUs of the CPT codes which are members of the same code families referenced for the previous CPT code, 78830: CPT codes 72191 (*Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing*) with a work RVU of 1.81, and 95863 (*Needle electromyography; 3 extremities with or without related paraspinal areas*) with a work RVU of 1.87. The physician time values of these services bracket those recommended for CPT code 778X1.

For CPT code 78832 (*Radiopharmaceutical localization of*

tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (e.g., pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days imaging), we disagree with the RUC recommendation to assign a work RVU of 2.23 based on the survey 50th percentile to this code, as this would value this code more highly than services of similar time values. To maintain relativity among services in this family, we proposed a work RVU of 2.12 based on the RUC-recommended incremental relationship between this code and CPT code 78803 (a difference of 1.03 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 2.12, we reference CPT code 70554 (*Magnetic resonance imaging, brain, functional MRI; including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration*), which has a work RVU of 2.11 and physician intraservice and total time values that are identical to those recommended for this service.

For CPT code 78835 (*Radiopharmaceutical quantification measurement(s) single area*), we disagree with the RUC recommendation to assign a work RVU of 0.51 based on the survey 25th percentile to this code, because we want to maintain relativity and proportionality among codes of this family. We based our values for the other codes in this family on their relative relationship to either CPT code 78800 or 78832, depending on the type of service described by the code. For CPT code 78830, which describes a single day of imaging and is thus analogous to CPT code 78835 in terms of units of service, our analysis indicates a reduction from the RUC value of approximately 7 percent is appropriate. Therefore, we apply a similar reduction of 7 percent to the RUC-recommended work RVU of 0.51 to arrive at an RVU of 0.47. We support this value by noting that it is bracketed by add-on CPT codes 77001 (*Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (List separately in addition to code for primary procedure)*) with a work RVU of 0.38, and 77002 (*Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)*), with a work RVU of 0.54. Both of these reference CPT codes have intraservice time values that are similar to, and total time values that are identical to, those recommended for CPT code 78835.

For the direct PE inputs, we are refining the number of minutes of clinical labor allocated to the activity ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' to the 2-minute standard for CPT codes 78800, 78801, 78802, 78804, 78803, 78830, 78831, and 78832, as no rationale was provided for these codes to have times above the standard for this activity. We are also refining the equipment time formulas to reflect this clinical labor refinement for these codes. For CPT codes 78800, 78801, 78802, 78804, 78803, 78830, 78831, and 78832, we proposed to refine the equipment times to match our standard equipment time formula for the professional PACS workstation. For the supply item SM022 ''sanitizing cloth-wipe (surface, instruments, equipment),'' we proposed to refine these supplies to quantities of 5 each for CPT codes 78801, 78804, and 78832 to conform with other codes in the family.

We received public comments on the proposed valuation of the codes in the SPECT–CT Procedures family. The following is a summary of the comments we received and our responses.

Comment: A commenter disagreed with our proposal which revalues these codes based on a total time ratio to value CPT code 78800 and increments between CPT code 78800 and CPT codes 78801, 78802, and 78804, and maintains the current value for CPT code 78803 and uses increments between the latter code and CPT codes 78830, 78831, and 78832. According to this commenter, our proposal is inappropriate, as it relies on an invalid total time ratio methodology to value CPT code 78800, and this time ratio methodology contradicts our stated position that we do not consider decrease in time as reflected in survey values equates to a one-to-one or linear decrease in the valuation of work RVUs.

Response: We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in Section 2, Methodology for Establishing Work RVUs (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: One commenter stated that the methodology used in the original valuation of CPT codes 78800, 78801, and 78803 is unknown and not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. This code's source of time is Harvard, implying that the time was merely extrapolated and not measured directly. The commenter noted that CMS' continued practice of referencing physician times and derived intensities created almost 30 years ago under the Harvard study as a method to critique RUC recommendations is not appropriate. The commenter also stated that the Harvard study employed much less rigor when determining physician time relative to the modern RUC/CMS process.

Response: We believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: For CPT Code 78835, a commenter stated that our application of a percentage reduction to a RUC recommendation is inappropriate and

not resourced based. The work of add-on code 78835 is a separate tangential service where the physician interprets and reviews a processed quantitated dataset and quality control information. Although 78835 is an add-on code for SPECT–CT, the commenter stated that the work of the add-on code differs markedly from the work of supervising and interpreting the SPECT–CT images themselves. The physicians not only reviews and interprets the dataset, but also commonly will redraw and reprocess to ensure reproducibility as they compare to prior images or datasets. The commenter stated that decisions are often discussed with referring physicians for improvement or decline of patients' area of interest status, and therefore, this is a very intense service as patient management will rely heavily on the quantitative comparisons.

Response: We continue to believe that applying a percentage reduction to the RUC-recommended value in this instance is an appropriate method of maintaining relativity among these services. Our proposed valuation for this service is consistent with other add-on codes of similar time, and maintains relative value with the other codes in the code family. In addition, we note that the intensity measure which results from our proposed value is essentially identical to that derived from the RUC-recommended value; the difference is only 0.002 of IWPUT. For these reasons, we believe that our proposed work RVU adequately captures the inherent intensity, and we note that the intensity value that results from our work RVU is virtually identical to that which results from the RUC value.

Comment: Commenters disagreed with our refinement to the clinical labor minutes allocated for the CA016 activity, and stated that the additional minute(s) above the standard PE 2 minutes is to account for the additional handling of the radiotracers or setting up the patient in the camera.

Response: We appreciate the additional information provided by the commenter, and in response to public comment, we are not finalizing our proposed refinements to the minutes allocated to the CA016 activity, and we are instead finalizing the RUC-recommended time inputs for this activity for all of the codes in the family.

Comment: A commenter disagreed with our proposed refinements to the SM022 supply item, used to clean the nuclear medicine equipment room and the room to receive and measure the radiotracers. The commenter stated that, if the imaging is typically over 2 days, then 10 items are needed. Also, if there are two radiotracers, then 10 not 5 of the wipes are needed because some of the wipes are used on camera and the area where the patient is given the injection(s) and others are used for the place where you receive and then go back to draw up the radiotracers.

Response: In response to public comment, we are not finalizing our proposed refinement, and instead are adopting the RUC-recommended quantities of the SM022 supply item.

Comment: One commenter sent invoices to update the price for the ''gamma camera system, single-dual head SPECT CT'' (ER097) equipment. The commenter stated that an average and typical negotiated price is $750,000 for this piece of equipment and that the CMS price for ER097 was undervaluing these services. The commenter urged CMS to update this equipment input price so that the reviewed procedures would be assessed appropriately and remain relative in valuation to other planar, SPECT, PET or PET–CT nuclear medicine services.

Response: We appreciate the submission of additional invoices from the commenter for use in pricing the ER097 gamma camera system. We are finalizing an increase in the price of this equipment item from the proposed $464,428.95 to $703,443.37 based on the submission of five invoices. Because the invoices for the ER097 gamma camera system were submitted as part of a revaluation or comprehensive review of a code family, this updated pricing will be fully implemented immediately for CY 2020 rather than being phased in over the 4-year supply and equipment pricing transition. (For additional details on this policy finalized in CY 2019, see 83 FR 59474 in the CY 2019 PFS final rule.)

After consideration of the public comments, we are finalizing our proposed work RVUs and direct PE refinements, with the exception of the CA016 clinical labor activity and SM022 supply item, for which we are finalizing the RUC-recommended labor times and quantities.

(51) Myocardial PET (CPT Codes 78459, 78429, 78491, 78430, 78492, 78431, 78432, 78433, and 78434)

CPT code 78492 (Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress) was identified via the High Volume Growth screen with total Medicare utilization over 10,000 that increased by at least 100 percent from 2009 through 2014. The CPT Editorial Panel revised this code set to reflect newer technology aspects such as wall motion, ejection fraction, flow reserve, and technology updates for hardware and software. The CPT Editorial Panel deleted a Category III code, added six Category I codes, and revised the three existing codes to separately identify component services included for myocardial imaging using positron emission tomography.

For CPT code 78491 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic)*), we disagreed with the RUC-recommended work RVU of 1.56, which is the survey 25th percentile value, as we believed that the 30-minute reduction in intraservice time and 15-minute reduction in physician total time does not validate an increase in work RVU, and we believed that the significance of the reductions in recommended physician time values warranted a reduction in work RVU. We proposed a work RVU of 1.00 based on the following total time ratio: The recommended 30 minutes divided by the current 45 minutes multiplied by the current work RVU of 1.50, which results in a work RVU of 1.00. As further support for this value, we note that it falls between CPT code 78278 (*Acute gastrointestinal blood loss imaging*), with a work RVU of 0.99, and CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), with a work RVU of 1.03.

For CPT code 78430 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan),* we disagreed with the RUC recommendation of 1.67 based on the survey 25th percentile, as we did not agree this service would be appropriately valued with an RVU that is among the highest of all services of similar times with this global period. We proposed a work RVU of 1.11 by applying the RUC-recommended increment between CPT code 78491 and this code, an increment of 0.11, to our proposed value of 1.00 for CPT code 78491, thus maintaining the RUC's recommended incremental relationship between these codes. As further support for this value, we noted that it falls between CPT codes 95977 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters,*

responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/ transmitter programming by physician or other qualified health care professional)), with a work RVU of 0.97, and CPT code 93284 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system*), with a work RVU of 1.25; both of these codes have similar physician time values.

For CPT code 78459 (*Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study*), we disagreed with the RUC recommendation to increase the work RVU to 1.61 based on the survey 25th percentile. We believed that the magnitude of the recommended reductions in physician time (a 50-minute reduction in intraservice time and a 32-minute reduction in total time) suggests that this value is overestimated; furthermore, we note that the RUC's recommendation is among the highest for all XXX-global period codes, or codes for which the global period concept does not apply, with similar time values. We proposed a work RVU of 1.05 by applying the RUC-recommended increment between this code and CPT code 78491, a difference of 0.05, which we applied to our proposed value for the latter code. We support our RVU of 1.05 by referencing two CPT codes: 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), and 36440 (*Push transfusion, blood, 2 years or younger*), both of which have work RVUs of 1.03, as well as identical intraservice and similar total time values.

We disagreed with the RUC's recommended valuation of 1.76 for CPT code 78429 (*Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study; with concurrently acquired computed tomography transmission scan*), which is based on the survey 25th percentile, because we believed a work RVU that is greater than those of all other services of similar intraservice time values is not appropriate. We proposed a work RVU of 1.20 for CPT code 78429. We proposed to value CPT code 78429 with an incremental methodology, which preserves the RUC-recommended relationship among the codes in this family; the RUC recommends an increment of 0.20 between CPT code 78429 and CPT code 78491. We proposed to apply this increment to our proposed value of 1.00 for CPT code 78491 to arrive at our value of 1.20.

We disagreed with the RUC's recommendation of 1.80 for CPT code 78492 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); multiple studies at rest and stress (exercise or pharmacologic)*) given the magnitude of the recommended reduction in physician time values (a 35-minute reduction in intraservice time and a 17-minute reduction in total time), and also given the fact that the RUC's recommended value would be the highest of all codes of this intraservice time and global period. We proposed a work RVU of 1.24 based on the RUC-recommended incremental difference between 78491 and 78492 of 0.24, which we add to our proposed value for 78491 for a work RVU of 1.24. As further support for this value, we referenced CPT code 95908 (*Nerve conduction studies; 3–4 studies*), with a work RVU of 1.25, similar physician time values.

We disagreed with the RUC's recommendation of 1.90 for CPT code 78431 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan*) which is based on a crosswalk to CPT code 64617 (*Chemodenervation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed*), because the fact that this work RVU is greater than those of all other services of similar intraservice time values suggested that it is an overestimate. Instead we proposed a work RVU of 1.34 for CPT code 78431, based on an incremental methodology. We apply the RUC-recommended increment between 78491 and CPT code 78431, a difference of 0.34, to our proposed value of 1.00 for CPT code 78491, for a value of 1.34. We supported this value by referencing CPT code 77261 (*Therapeutic radiology treatment planning; simple*), with a work RVU of 1.30, and CPT code 94003 (*Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day*), with a work RVU of 1.37. These codes have similar physician time values.

We disagreed with the RUC's recommendation of 2.07 for CPT code 78432 (*Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (e.g., myocardial viability)*), because we believed the fact that this work RVU is greater than those of all other services of similar intraservice time values suggests that it is an overestimate. We proposed a work RVU of 1.51 for CPT code 78432, based on an incremental methodology. We applied the RUC-recommended increment between 78491 and CPT code 78432, a difference of 0.51, to our proposed value of 1.00 for CPT code 78491, for a value of 1.51. We support this value by referencing CPT code 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*), with a work RVU of 1.46, and similar physician time values.

Similarly for CPT code 78433 (*Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan*), we disagreed with the RUC's recommendation of 2.26 based on a crosswalk to CPT code 71552 (*Magnetic resonance (e.g., proton) imaging, chest (e.g., for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s), followed by contrast material(s) and further sequences*), because we believed the fact that this work RVU is among the highest among services of similar intraservice time values suggests that it is an overestimate. We proposed a work RVU of 1.70 by applying the RUC-recommended increment between CPT code 78433 and CPT code 78491, which is a difference of 0.70, to our proposed value for CPT code 78491 for a value of 1.70. We supported this value by referencing CPT codes 95924 (*Testing of autonomic nervous system function; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt*) and 74182 (*Magnetic resonance (e.g., proton) imaging, abdomen; with contrast material(s)*), both of which have work RVUs of 1.73.

For CPT code 78434 (*Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography, rest and pharmacologic stress (List separately in addition to code for primary procedure)*), we disagreed with the RUC recommendation to assign a work RVU of 0.63 to this code based on the survey 25th percentile, because we believed a comparison to other codes with a global period of ZZZ (add-on codes) suggests that this is somewhat overvalued, and because we want to maintain relativity and proportionality to other codes in this series. We based our values for the other codes in this family on their relative relationships to CPT code 78491; for that code our analysis indicates that a reduction from the RUC value of roughly ⅓ is appropriate, based on a ratio of the decrease in total time to the current work RVU. Therefore, we apply a similar reduction of ⅓ to the RUC-recommended work RVU of 0.63 to arrive at an RVU of approximately 0.42. Applying a reduction that is similar to the reduction we believe is warranted from the RUC value for CPT code 78491 to CPT code 78434 will maintain consistency in value among these services We believed this work RVU is validated by noting that it is bracketed by CPT codes 15272 (*Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)*), with a work RVU of 0.33, and 11105 (*Punch biopsy of skin (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)*), with a work RVU of 0.45. A work RVU of 0.42 is thus consistent with ZZZ global period codes of similar physician times.

For the direct PE inputs, for several of the equipment items, we proposed to refine the equipment times to conform to our established policies for non-highly, as well as for highly technical equipment. (For the highly technical equipment standard, please see the discussion in the CY 2013 PFS final rule, 77 FR 69028.) In addition, we proposed to refine the equipment times to conform to our established policies for PACS Workstation. For the new equipment items ER110: ''PET Refurbished Imaging Cardiac Configuration'' and ER111: ''PET/CT Imaging Camera Cardiac Configuration,'' we proposed to assume that a 90 percent equipment utilization rate is typical, as this would be consistent with our equipment utilization assumptions for expensive diagnostic imaging equipment. For the supply item SM022 ''sanitizing cloth-wipe (surface, instruments, equipment),'' we proposed to refine these supplies to quantities of 5 each for CPT codes 78432 and 78433 to conform with other codes in the family. We proposed that we will not price the ''Software and hardware package for Absolute Quantitation'' as a new equipment item, due to the fact that the submitted invoices included a service contract and a combined software/hardware bundle with no breakdown on individual pricing. Based on our lack of specific pricing data, we believe that this software is more accurately characterized as an indirect PE input that is not individually allocable to a particular patient for a particular service.

We received public comments on the proposed valuation of the codes in the Myocardial PET family. The following is a summary of the comments we received and our responses.

Comment: A commenter noted that the values published in the text of the 2020 PFS proposed rule do not match those posted in Table 20: Proposed CY 2020 Work RVUs for New, Revised and Potentially Misvalued Codes and in Addendum B.

Response: We regret that we have posted inaccurate values in the proposed rule Addenda and in Table 20. Our proposed work RVUs are accurately reflected in the text of the proposed rule.

Comment: A few commenters disagreed with our proposed work RVUs for CPT codes 78459, 78429, 78491, 78430, 78492, 78431, 78432, and 78433, stating that our use of a time ratio to value CPT code 78491 is invalid, as it treats all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity. Similarly, the commenter stated that our use of increments to value CPT codes 78459, 78429, 78430, 78492, 78431, 78432, and 78433 is inappropriate as it treats all components of the physician time as having identical intensity. The commenter stated that our proposed values for these codes vastly underestimate the physician work required to perform these services.

These commenters stated that our proposed valuations for these codes take no account of the fact that the physician work involved with these services has changed, and that substantial changes in instrumentation, hardware and software have occurred since these codes were created.

Response: As discussed in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), we continue to believe that time ratios are one of several appropriate methodologies for valuing services. However, we are persuaded that examining the changes in physician time for these services alone may not adequately reflect increases in intensity due to changes in technology for these services. We are persuaded by the comments that suggest that these codes describe services that have changed substantially over time. After consideration of the public comment, and in the interest of payment stability and protecting patient access for these services, we are not finalizing the proposed work RVUs for these services and instead are adopting the RUC-recommended work RVUs for these services.

Comment: Many commenters stated that moving from contractor pricing to active pricing for the technical component (TC) of these services using inputs as proposed will result in drastic reductions in payment rates for these services. These commenters stated that our proposal will result in a roughly 80 percent reduction in payments for the TC, and that this reduction will effectively eliminate access to Myocardial PET. Commenters stated that the RUC recommended direct PE inputs understate technical costs. Commenters discussed the importance of this service as a non-invasive diagnostic tool which they stated is superior to conventional nuclear cardiology and reduces the need for coronary angiography and coronary interventions. Commenters offered detailed evidence on the efficacy of PET and its usefulness in reducing mortalities and morbidities; this evidence includes a study which demonstrates that in patients being evaluated for suspected coronary artery disease, Cardiac PET results in a 50 percent reduction in the use of coronary arteriography and CABG and a 30 percent reduction in direct patient management costs, while maintaining excellent patient outcomes and minimizing indirect costs. Commenters noted other studies demonstrate the effectiveness of PET as a diagnostic tool when compared to other modalities for diagnosis of myocardial ischemia.

Commenters representing Cardiologists expressed support for the RUC process, however, they noted that they are alarmed at the proposed 75–80 percent reduction in the TC payment and stated it is not consistent with the amounts necessary to continue to operate a Cardiac PET facility. Further, they argued that the inputs used to calculate payment were incomplete and

inaccurate, which combined to trigger an unsustainable proposal. These commenters requested that we work with physicians, industry, and cardiologist representatives to improve the accuracy of all inputs used to generate the proposed CY 2020 RVUs, and they requested that CMS maintain payment at current levels pending an appropriate revision.

Response: As stressed by many commenters, adopting active pricing for the TC of these codes will result in significant reductions in payment. We believe there is substantial work to be done to assure the new valuations for the TCs of these codes accurately reflect the technical inputs. In the interest of maintaining payment stability and protecting patient access to these important services, we are delaying the adoption of active pricing for these codes until such time as more accurate sets of inputs can be developed, and we are maintaining contractor pricing for the TC of these services. CMS will continue to review the inputs, and encourage the public to submit additional information on the most accurate resource-based payment for these services by our annual February 10th deadline for consideration in future rulemaking.

Comment: One commenter disagreed with our proposed refinements to the SM022 supply item, used to clean the nuclear medicine equipment room and the room to receive and measure the radiotracers. The commenter stated that, if the imaging is typically over 2 days, then 10 items are needed. Also, if there are two radiotracers, then 10 not 5 of the wipes are needed because some of the wipes are used on camera and the area where the patient is given the injection(s) and others are used for the place where you receive and then go back to draw up the radiotracers.

Response: In response to public comment, we are not finalizing the proposed refinement and instead are finalizing the RUC-recommended quantities of the SM022 supply item.

Comment: Several commenters submitted invoices to update the price for the ''PET Refurbished Imaging Cardiac Configuration'' (ER110) and the ''PET/CT Imaging Camera Cardiac Configuration'' (ER111) equipment items. The commenters urged CMS to update these equipment prices in response to the additional data included on the invoices.

Response: We appreciate the submission of additional invoices from the commenters for use in pricing the ER110 and ER111 equipment items. We are finalizing an increase in the price of the ER110 ''PET Refurbished Imaging Cardiac Configuration'' equipment from the proposed $425,000 to $527,615.63 based on additional pricing data, from one submitted invoice to an average of ten invoices. We are finalizing an increase in the price of the ER111 ''PET/CT Imaging Camera Cardiac Configuration'' equipment from the proposed $1,232,226.44 to $1,364,960.59 based on additional pricing data, from an average of four submitted invoices to an average of eight invoices. We note that we also received an additional invoice for the ER111 equipment at a price of $3,206,811.30; however, due to the fact that this invoice was nearly triple the price of the other eight invoices, we did not include it in the overall average as it appears to be an outlier that is not representative of typical pricing.

Comment: Several commenters disagreed with the CMS proposal to refrain from establishing a price for the ''Software and hardware package for Absolute Quantitation'' as a new equipment item. Commenters stated that it was unreasonable for CMS to propose that the software should be removed, as historically all nuclear medicine hardware must have software to run them or they do not work. Commenters stated that practitioners must have both the hardware and software to analyze myocardial blood flow and that separating the software and hardware would render this system inoperable. One commenter urged CMS to price the software and hardware package for absolute quantitation as recommended while other commenters submitted additional invoices and asked CMS to use them for pricing.

Response: We stated in the proposed rule that we would not price the ''Software and hardware package for Absolute Quantitation'' as a new equipment item due to the fact that the submitted invoices included a service contract and a combined software/hardware bundle with no breakdown on individual pricing. We appreciate the submission of additional invoices from the commenters with more specific pricing information for this equipment without the inclusion of a service contract, which we continue to believe is a form of indirect PE. Therefore, we are finalizing the creation of ''Software and hardware package for Absolute Quantitation'' as a new equipment item (ER113) at a price of $44,652.33 based on the submission of six new invoices from the commenters.

Comment: One commenter stated that the pricing for the new PET Generator Infusion Cart (ER109) was incorrect. The commenter stated that the invoices used to establish the proposed price for the ER109 equipment were instead for the purchase of the ''generator'' that comes loaded with the radioactive rubidium 82. The commenter explained that the infusion cart is the machine that houses the rubidium generator and draws the rubidium tracer doses, and that the generator is a separate equipment item. The commenter provided four invoices for the purchase of the infusion cart itself, as well as several invoices for the monthly rental fee of an infusion cart.

Response: We appreciate the additional information provided by the commenter with regards to the PET generator and infusion cart, including the invoices for the monthly rental fee of an infusion cart. Based on the information provided by the commenter, we are finalizing a change to the name of the ER109 equipment item, which were are changing from ''PET Generator Infusion Cart'' to ''PET Infusion Cart'' to more accurately reflect the equipment in question. We are finalizing the price of the ER109 infusion cart at $74,225.47 based on the submission of four new invoices from the commenters. In light of the clarification provided by the commenters, we are also creating a new ER114 equipment item named ''PET Generator (Rubidium)'' to cover the cost of the generator. The price of the ER114 equipment remains unchanged from the proposed price of $47,052.80, which had mistakenly been applied to the ER109 infusion cart in the proposed rule, and we will assign the same equipment time to the ER114 generator as proposed for the ER109 infusion cart in CPT codes 78430, 78431, 78432, 78433, 78434, 78491, and 78492. We note as well for future reference that although we appreciated the submission of the rental invoices, we are unable to use invoices for a monthly rental fee to determine the typical purchase price for equipment. We believe that invoices for a monthly rental fee would not be representative of the purchase price for equipment, in the same fashion that the rental fee for a car differs from its purchase price.

Comment: One commenter supplied additional invoices for costs associated with Myocardial PET procedures that the commenter believed should be considered in pricing. The commenter stated that it was typical for building infrastructure improvements like enhanced load-bearing supports, lead-lining in the walls, and separate cooling systems to be necessary to install and maintain a PET machine. The commenter stated that payment rates that failed to account for the startup and maintenance costs necessary to provide high-quality imaging services to sick

patients would further disadvantage practices that provide Myocardial PET.

Response: We disagree with the commenter that these additional invoices constitute forms of direct PE. The commenter submitted two invoices for a ''Lead PET Cabinet'' which would be used for storage purposes. Under our PE methodology as detailed in the CY 2010 final rule with comment period (74 FR 61743–61748), this is considered to be an administrative cost which falls under indirect PE, similar to the expenses associated with office rent, as it is not a cost directly associated with the furnishing of the procedure. The commenter also submitted three invoices for a ''PET Service Contract'', which, as the name suggests, constitutes a service contract that we would also consider to be an administrative expense and a form of indirect PE. The details of this contract specify that it included ''maintenance, testing, and quality control'' for PET equipment; however, our equipment pricing formula already includes maintenance costs, and if we were to pay separately for this service contract, we would be paying duplicatively for this equipment. We agree with the commenter that there are significant costs associated with running a practice that furnishes services involving capital-intensive imaging equipment. However, under our PE methodology these costs are included under indirect PE in the form of administrative and office rent expenses, and it would be inaccurate and duplicative to include them as a separate direct PE cost.

Comment: Several commenters disagreed with the CMS proposal to assume that a 90 percent equipment utilization rate would be typical for the new ''PET Refurbished Imaging Cardiac Configuration'' (ER110) and ''PET/CT Imaging Camera Cardiac Configuration'' (ER111) equipment items. Commenters stated that they had collected data from the number of patients imaged with this equipment each day, which showed an overall average of 4.5 patients imaged per facility per day. Commenters stated that this work flow data equated to the equipment remaining in use for 5–6 hours each day, which was far lower than what a 90 percent utilization rate would suggest. Commenters noted that these PET services existed in 2010 when CMS made the decision to apply the 90 percent utilization rate only to CT and MRI services, and they were unaware of any changes in CMS policy or any statutory requirement to assume a 90 percent utilization rate for PET imaging. Commenters stated that experts that perform cardiac PET and PET–CT in the physician office and independent diagnostic testing facility (IDTF) settings confirmed that a 50 percent utilization would be a more accurate utilization rate and urged CMS to adopt the default utilization rate of 50 percent.

Response: We appreciate the submission of additional information from the commenters, particularly the work flow study data that indicated that the PET equipment typically remains in use for 5–6 hours per day. Based on the information from the commenters, we are not finalizing our proposal to assume a 90 percent utilization rate for the ER110 and ER111 equipment items, and we will instead finalize the default 50 percent utilization rate assumption for both equipment items.

Comment: A commenter stated that they were concerned about a rapid transition from contractor pricing to relative values that are significantly lower than current rates. The commenter stated that CMS should use the most current paid (2018) contractor claims for CPT codes 78459, 78491 and 78492 to establish a weighted average technical rate for each code, and then use its authority to phase in changes in payment so as not to disrupt services. The commenter acknowledged that it could be argued as to whether or not the phase-in provision applied to CPT codes 78459, 78491 and 78492, but urged CMS to phase in these codes and limit them to no more than a 20 percent reduction for the technical or global in any one year so as to not jeopardize patient access to care.

Response: Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. We proposed to exempt CPT codes 78459, 78491 and 78492 from the phase-in of significant RVU reductions required by section 1848(c)(7) of the Act due to the fact that they are moving from contractor-priced status to active pricing status; we believe that this constitutes a ''revised'' code for purposes of section 1848(c)(7) of the Act. We have also previously finalized a policy through rulemaking stating that significant coding revisions within a family of codes can change the relationships among codes to the extent that it changes the way that all services in the group are reported, even if some individual codes retain the same number or, in some cases, the same descriptor. Excluding codes from the phase-in when there are significant revisions to the code family also helps to maintain the appropriate rank order among codes in the family, avoiding years for which RVU changes for some codes in a family are in transition while others were fully implemented. We believe that either the shift from contractor-priced status to active pricing status or inclusion as part of a code family undergoing major revisions constitutes a ''revised'' code for purposes of section 1848(c)(7) of the Act. For additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70929).

After consideration of the public comments, we are not finalizing our proposed work RVUs, and are instead finalizing the RUC-recommended work RVUs. We are not finalizing our proposal to assign PE RVUs using direct PE inputs, and we are instead maintaining contractor pricing for the TC of these services.

(52) Cytopathology, Cervical-Vaginal (CPT Code 88141, HCPCS Codes G0124, G0141, and P3001)

CPT code 88141 (*Cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician*), HCPCS code G0124 (*Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician),* HCPCS code G0141 (*Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician*), and HCPCS code P3001 (*Screening Papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician*) were identified as potentially misvalued on a list of CMS or other source codes with Medicare utilization of 30,000 or more.

In the CY 2000 PFS final rule (64 FR 59408), we finalized a policy that it was more appropriate to evaluate the work, PE, and MP RVUs for HCPCS codes P3001, G0124, and G0141 identical or comparable to the values of CPT code 88141.

For CY 2020, the RUC recommended a work RVU of 0.42 for CPT code 88141 and HCPCS codes G0124, G0141, and P3001, based on the current value. We disagreed with the RUC-recommended work RVU and proposed a work RVU of 0.26 for all four codes in this family, based on our intraservice time ratio methodology and a crosswalk to CPT code 93313 (*Echocardiography, transesophageal, real-time with image*

documentation (2D) (with or without M-mode recording); placement of transesophageal probe only), which has an identical work RVU of 0.26, identical intraservice and total work times values to CPT code 88141 and HCPCS codes G0124, and G0141, and similar intraservice and total time values to HCPCS code P3001.

In reviewing this family of codes, we noted that the intraservice and total work times for CPT code 88141 and HCPCS codes G0124, and G0141 are decreasing from 16 minutes to 10 minutes (38 percent reduction) and the intraservice and total work times for HCPCS code P3001 are decreasing from 16 minutes to 12 minutes (25 percent reduction). However, the RUC recommended a work RVU of 0.42 for all four codes in this family, based on the maintaining the current work RVU. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 88141 and HCPCS codes G0124, G0141, and P3001, we believed that it would be more accurate to propose a work RVU of 0.26, based on our intraservice time ratio methodology and a crosswalk to CPT code 93313 to account for these decreases in the surveyed work times.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Perform regulatory mandated quality assurance activity'' (CA033) activity from 7 minutes to 5 minutes for all four codes in the family. We believed that these quality assurance activities would not typically take 7 minutes to perform, given that similar federally mandated Mammography Quality Standards Act (MQSA) activities were recommended and finalized at a time of 4 minutes for CPT codes 77065–77067 in CY 2017 (81 FR 80314–80316), and other related regulatory compliance activities were recommended and finalized at a time of 5 minutes for CPT codes 78012–78014 in CY 2013 (77 FR 69037). To preserve relativity between services, we proposed a clinical labor time of 5 minutes for the codes in this family based on this prior allocation of clinical labor time.

We are also proposed to remove the 1-minute of clinical labor time for the ''File specimen, supplies, and other materials'' (PA008) activity from all four codes under the rationale that this task is a form of indirect PE. As we stated in the CY 2017 PFS final rule (81 FR 80324), we agree that filing specimens is an important task, and we agree that these would take more than zero minutes to perform. However, we continue to believe that these activities are correctly categorized under indirect PE as administrative functions, and therefore, we do not recognize the filing of specimens as a direct PE input, and we do not consider this task as typically performed by clinical labor on a per-service basis.

We proposed to refine the equipment time for the compound microscope (EP024) equipment to 10 minutes for all four codes in the family to match the work time of the procedures. The recommended materials for this code family state that the compound microscope is utilized by the pathologist, and therefore, we believe that the 10-minute work time of the procedures would be the most accurate equipment time to propose.

We received public comments on the proposed valuation of the codes in the Cytopathology, Cervical-Vaginal family. The following is a summary of the comments we received and our responses.

Comment: A commenter disagreed with the proposed work RVUs for CPT Code 88141, and HCPCS codes G0124, G0141, and P3001. This commenter stated that it is clear that CMS misinterpreted the RUC's recommendations because lowering the work value of code P3001, using what the commenter referred to as the ''CMS' 25 percent time ratio methodology,'' would equate to a work RVU of 0.32, not 0.26 as proposed. This commenter also urged CMS to discontinue its arbitrary use of invalid time components, invalid methodologies using time ratios, and other irrational uses of data to value physician services.

Response: We note that we correctly interpreted the RUC's recommendations, and correctly applied a time ratio methodology to develop the proposed work RVUs for the codes in this family. We also considered an existing policy set forth in the CY 2000 PFS final rule (64 FR 59408), for these services to develop our proposed values. The RUC recommended maintaining the existing work RVU for all four codes in this family, which is a work RVU of 0.42. In our review of the codes in this family, the intraservice time ratio for CPT code 88141, suggest CPT code 88141 is better valued at a work RVU of 0.26. We note, that in an existing policy related to these four codes, discussed in the CY 2000 PFS final rule (64 FR 59408), we finalized a policy that it was more appropriate to evaluate the work, PE, and MP RVUs for HCPCS codes P3001, G0124, and G0141 identical or comparable to the values of CPT code 88141. Thus, we proposed an identical work RVU of 0.26 for all four codes in this family, such that the proposed work RVU for HCPCS codes P3001, G0124, and G0141 are valued identical to CPT code 88141. We note that the RUC recommended that we maintain the same work RVU for all four codes in this family, and did not recommend a different work RVU for HCPCS P3001.

We also clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). With regards to the invocation of clinically relevant relationships by the commenters, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters disagreed with the proposed work RVUs for CPT Code 88141, and HCPCS codes G0124, G0141, and P3001. Commenters stated that CMS should instead finalize the RUC-recommended work RVUs for these procedures. Commenters disagreed with our reference to older work time sources, and noted that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not

surveyed, and therefore, were not resource-based. Commenters noted that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC for the services.

Response: We appreciate the commenters' concerns regarding CMS' interpretation of older work time sources and their use in the code valuation process for establishing work RVUs for these services. We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Based on the aforementioned crosswalks, we continue to believe the proposed values better preserve relativity with the rest of the codes on the PFS.

Comment: Several commenters disagreed with the CMS proposal to refine the clinical labor time for the ''Perform regulatory mandated quality assurance activity'' (CA033) activity from 7 minutes to 5 minutes for all four codes in the family. Commenters stated that laboratories which process and interpret gynecologic cytology are extensively regulated, and the commenters listed a series of different exercises that must take place in slide reexamination. Commenters stated that cytotechnologists are required to record the number of slides examined, the type of preparation, and the amount of time spent in slide examination. Commenters also stated that pap tests are highly litigated and perhaps relatively poorly paid procedures, and that the need for extensive QA and QC procedures and risk of litigation is a serious disincentive for providing this service.

Response: We appreciate the additional information provided by the commenters regarding the types of quality assurance activities that take place during these procedures. However, commenters did not address our rationale for proposing this refinement to the CA033 clinical labor activity, which was the previous finalization of 4 minutes for similar federally mandated MQSA activities in CPT codes 77065–77067 and 5 minutes for CPT codes 78012–78014. We did not receive information from the commenters regarding how the quality assurance activities taking place in the codes in this family would be different from the similar quality assurance activities finalized in previous rulemaking, or provide a rationale for why additional time would typically be required for the reviewed codes. We continue to believe that a clinical labor time of 5 minutes is the most accurate valuation for the CA033 clinical labor activity to preserve relativity between services based on this prior allocation of clinical labor time.

Comment: Several commenters disagreed with the CMS proposal to remove the 1-minute of clinical labor time for the ''File specimen, supplies, and other materials'' (PA008) activity from all four codes under the rationale that this task is a form of indirect PE. Commenters stated that these tasks must be performed for each individual patient case and that the results are manually entered in most facilities. Commenters stated that the laboratory technician carefully reviews, double checks the information, and enters the reporting results into the laboratory information system. Commenters stated that 1 minute for this task was very typical and appropriate for this service.

Response: As we stated in the CY 2017 PFS final rule (81 FR 80324) and again in the proposed rule, we agree that filing specimens is an important task, and we agree that it would take more than zero minutes to perform. However, we continue to believe that these activities are correctly categorized under indirect PE as administrative functions, and therefore, we do not recognize the filing of specimens as a direct PE input, and we do not consider this task as typically performed by clinical labor on a per-service basis.

Comment: Several commenters disagreed with the CMS proposal to refine the equipment time for the compound microscope (EP024) equipment to 10 minutes for all four codes in the family to match the work time of the procedures. Commenters stated that the microscope is utilized by the pathologist for the entire physician time, and, in addition, the cytotechnologist uses a different microscope for at least 4 minutes to assist in the performance of regulatory mandated quality assurance activities. Commenters urged CMS to finalize the RUC-recommended PE recommendations for CPT codes 88141, G0124, G0141, and P3001.

Response: We appreciate the additional information provided by the commenters regarding the use of the compound microscope by the cytotechnologist in these procedures. Based on the information provided by the commenters, we are not finalizing our proposed refinement to the equipment time for the compound microscope (EP024) equipment. We are instead finalizing the RUC-recommended equipment time for all four codes in the family.

After consideration of the public comments we are finalizing the work RVUs for the codes in this family as proposed. We are also finalizing our direct PE refinements as proposed, with the exception of the compound microscope (EP024) equipment time as detailed above.

(53) Biofeedback Training (CPT Codes 90912 and 90913)

CPT code 90911 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry*) was identified as potentially misvalued on a RAW screen of codes with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS or other source codes. In September 2018, the CPT Editorial Panel replaced this code with two new codes to describe biofeedback training initial 15 minutes of one-on-one patient contact and each additional 15 minutes of biofeedback training.

We proposed the RUC-recommended work RVU of 0.90 for CPT code 90912 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry when performed; initial 15 minutes of one-on-one patient contact*), as well as the RUC-recommended work RVU of 0.50 for CPT code 90913 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry when performed; each additional 15 minutes of one-on-one patient contact*). For the direct PE inputs, we proposed to refine the equipment time for the power table (EF031) equipment in CPT code 90912 to conform to our established policies for non-highly technical equipment.

We are also proposing to designate CPT codes 90912 and 90913 as ''sometimes therapy'' procedures which means that an appropriate therapy modifier is always required when this service is furnished by therapists. For

more information we direct readers to the Therapy Code List section of the CMS website at *https://www.cms.gov/Medicare/Billing/TherapyServices/AnnualTherapyUpdate.html.*

We received public comments on the proposed valuation of the codes in the Biofeedback Training family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposal of the RUC-recommended work RVU for both codes in the family. Another commenter agreed with the proposal to designate both procedures as ''sometimes therapy'', as they are performed in a physician's office and will not require the use of the modifier for physical therapy, occupational therapy, or speech-language pathology plan of care.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Biofeedback Training family as proposed. We are also finalizing the proposal to designate CPT codes 90912 and 90913 as ''sometimes therapy'' procedures.

(54) Corneal Hysteresis Determination (CPT Code 92145)

In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the AMA/Specialty Society RVS Update Committee. The AMA RUC reviewed this service at the October 2018 RAW meeting, and indicated that the utilization is continuing to increase for this service. This code was surveyed and reviewed for the January 2019 RUC meeting.

We proposed the work RVU of 0.10 as recommended by the RUC. We also proposed the RUC-recommended direct PE inputs for CPT code 92145 without refinement.

We received public comments on the proposed valuation of CPT code 92145 for Corneal Hysteresis Determination. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of our proposal of the RUC-recommended work RVUs.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs and direct PE inputs for Corneal Hysteresis Determination (CPT code 92145).

(55) Computerized Dynamic Posturography (CPT Codes 92548 and 92549)

CPT code 92548 (*Computerized dynamic posturography*) was identified via the negative IWPUT screen. CPT revised one code and added another code to more accurately describe the current clinical work and equipment necessary to provide this service.

We do not agree with the RUC's recommended work RVUs of 0.76 for CPT code 92548 (*Computerized dynamic posturography sensory organization test (CDP–SOT), 6 conditions (i.e., eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report*), or 0.96 for CPT code 92549 (*Computerized dynamic posturography sensory organization test (CDP–SOT), 6 conditions (i.e., eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT)*). For CPT code 92548, we agree that an increase in work RVU is warranted; however, we believe the surveyed time values suggest an increase of a less significant magnitude than that recommended. We proposed a work RVU of 0.67 based on the intraservice time ratio: we divide the RUC-recommended intraservice time value of 20 by the current value of 15 and multiply the product by the current work RVU of 0.50 for a ratio of 0.67. As a supporting crosswalk, we note that our value is greater than the work RVU of 0.60 for CPT code 93316 (*Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only*), which has identical intraservice and total times.

We proposed to maintain relativity between these two codes by valuing CPT code 92549 by applying the RUC-recommended incremental difference between the two codes, a difference of 0.20, to our proposed value of 0.67 for CPT code 93316; therefore, we proposed a work RVU of 0.87 for CPT code 92549. As further support for this value, we note that it falls between the work RVUs of CPT codes 95972 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*), with a work RVU of 0.80, and CPT code 38207 (*Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage*), with a work RVU of 0.89.

We proposed the RUC-recommended direct PE inputs for these codes without refinement.

We received public comments on the proposed valuation of the codes in the Computerized Dynamic Posturography family. The following is a summary of the comments we received and our responses.

Comment: A commenter objected to our proposed work RVUs for these codes, stating that they relied inappropriately on a time ratio to value CPT code 92548, and that use of a time ratio represents a flawed methodology. Furthermore, the commenter stated that we incorrectly referred to our supporting reference CPT code 93316 as a ''crosswalk,'' as this code does not have a work RVU equivalent to what we are proposing for CPT code 92548.

Response: We regret that the values posted in Addendum B and in table 20 of the proposed rule do not match those in the text of proposed rule. We reiterate that we proposed work RVUs of 0.67 for CPT code 92548 and 0.87 for CPT code 92549 as discussed above, as well as in the text of the proposed rule (84 FR 40596). We agree that CPT code 93316 is more appropriately termed a reference code rather than a crosswalk. We continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular services, and we refer readers to the ''Methodology for Establishing Work RVUs'' (section II.N.2. of this final rule) for a fuller discussion.

Comment: A commenter stated that our valuation of CPT code 92549, which is based on the RUC-recommended incremental relationship between this code and CPT code 92548 is an invalid methodology.

Response: We continue to believe that an analysis that includes RUC-recommended incremental relationships between codes is an appropriate methodology for estimating accurate relative value among services. We believe that use of the increment, as well as reference to bracketing CPT codes 95972 and 38207, the latter of which has higher time values than CPT 92549, validates our proposed work RVU.

Comment: Several commenters requested that CMS phase in the proposed cuts for CPT codes 92548 and 92549 under the authority provided by the ''Protecting Access to Medicare Act of 2014'' (Pub. L. 113–93) which requires a 2-year phase-in of payment reductions that exceed 20 percent. The commenters stated that these codes define services that are not new, rather they were clarified by CPT as noted by the retention of the same CPT code. Commenters stated that the services are now more clearly defined, in the interest of program integrity, but the services themselves have not changed.

Response: Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. CPT code 92549 is exempt from the phase-in of significant RVU reductions required by section 1848(c)(7) of the Act because it is a new code, and the statute explicitly states that the phase-in does not apply to new codes. We proposed to exempt CPT code 92548 from the phase-in due to the fact that it is part of the same family of codes that included new CPT code 92549. We have previously finalized this policy through rulemaking, stating that significant coding revisions within a family of codes can change the relationships among codes to the extent that it changes the way that all services in the group are reported, even if some individual codes retain the same number or, in some cases, the same descriptor. Excluding codes from the phase-in when there are significant revisions to the code family also helps to maintain the appropriate rank order among codes in the family, avoiding years for which RVU changes for some codes in a family are in transition while others were fully implemented. In addition, the code descriptor for CPT code 92548 was significantly changed by CPT as part of this review, which we believe meets the criteria of ''revised'' as detailed in the statute. For additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70929).

After consideration of the public comments, we are finalizing our proposed work RVUs and the RUC-recommended direct PE inputs.

(56) Auditory Function Evaluation (CPT Codes 92626 and 92627)

CPT code 92626 (*Evaluation of auditory function for surgically implanted device(s), candidacy or post-operative status of a surgically implanted device(s); first hour*) appeared on the RAW 2016 high volume growth screen. In 2017, it was identified through a CMS request. CPT code 92627 (*Evaluation of auditory function for surgically implanted device(s), candidacy or post-operative status of a surgically implanted device(s); each additional 15 minutes*) the add-on code for CPT code for 92626, also was included in the CMS request to review audiology services.

For CY 2020, we proposed the HCPAC-recommended work RVU of 1.40 for CPT code 92626, which is identical to its current RVU. We also proposed the HCPAC-recommended work RVU of 0.33 for the add-on code, CPT code 92627. We proposed the RUC-recommended direct PE inputs for both codes.

We received several comments on the proposed valuations of the Auditory Function Evaluation codes. All commenters expressed support for our recommended RVU values for the 2020 final rule. After consideration of the public comments, we are finalizing the proposed work RVUs and direct PE inputs for CPT codes 92926 and 92927.

(57) Septostomy (CPT Codes 92992 and 92993)

CPT codes 92992 (*Atrial septectomy or septostomy; transvenous method, balloon (e.g., Rashkind type) (includes cardiac catheterization)*) and 92993 (*Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)*) were nominated as potentially misvalued services. These services are typically performed on children, a non-Medicare population, and are currently contractor-priced. These codes were surveyed and reviewed for the January 2019 RUC meeting.

We proposed to maintain contractor pricing for CPT codes 92992 and 92993, as recommended by the RUC. These codes will be referred to the CPT Editorial Panel for revision and potential deletion. We also proposed a change from 90-day to 0-day global period status for these two procedures, also as recommended by the RUC.

We received public comments on the proposed valuation of the codes in the Septostomy family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposals to maintain contractor pricing for CPT codes 92992 and 92993 and to change from 90-day to 0-day global period status for these two procedures.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing contractor pricing for CPT codes 92992 and 92993 as proposed, as well as a change from 90-day to 0-day global period status for these two procedures.

(58) Ophthalmoscopy (CPT Codes 92201 and 92202)

CPT code 92225 was identified as potentially misvalued on a screen of codes with a negative IWPUT, with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. In February 2018, the CPT Editorial Panel deleted CPT codes 92225 and 92226 and created two new codes to specify what portion of the eye is examined for a service beyond the normal comprehensive eye exam.

We proposed the RUC-recommended work RVUs of 0.40 for CPT code 92201 (*Ophthalmoscopy, extended, with retinal drawing and scleral depression of peripheral retinal disease (e.g., for retinal tear, retinal detachment, retinal tumor) with interpretation and report, unilateral or bilateral*) and 0.26 for CPT code 92202 (*Ophthalmoscopy, extended, with drawing of optic nerve or macula (e.g., for glaucoma, macular pathology, tumor) with interpretation and report, unilateral or bilateral*).

We proposed the RUC-recommended direct PE inputs for this code family without refinement.

We received public comments on the proposed valuation of the codes in the Ophthalmoscopy family. The following is a summary of the comments we received and our responses.

Comment: A commenter supported our proposal to use the RUC-recommended work RVU for this code.

Response: We appreciate the support for our proposal from the commenters.

After consideration of the public comments, we are finalizing work RVUs as proposed. We are also finalizing the direct PE inputs as proposed.

(59) Remote Interrogation Device Evaluation (CPT Codes 93297, 93298, 93299, and HCPCS code G2066)

When the RUC previously reviewed the CPT code 93299 at the January 2017 RUC meeting, the specialty society submitted PE inputs for CPT code 93299 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm*

monitor system, remote data acquisitions(s), receipt of transmissions and technician review, technical support and distribution of results); the PE Subcommittee and RUC accepted the society recommendations. In the CY 2018 PFS final rule (82 FR 53064), we did not finalize our proposal to establish national pricing for CPT code 93299 and the code remained contractor-priced.

At the October 2018 RUC meeting, the RUC re-examined CPT code 93299. CPT codes 93297 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional*) and 93298 (*Interrogation device evaluation(s), remote up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis or recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional*) were added to this family of services. These three codes were reviewed for PE only.

CPT codes 93297 and 93298 are work-only codes and CPT code 93299 is meant to serve as the catch-all for both 30-day remote monitoring services. The RUC is unclear why the code family was designed this way, noting it may have been a way to allow for the possibility that the technical work would be provided by vendors, but they noted that this is not how the service is currently provided. They stated that in the decade since these codes were created, it has become clear that implantable cardiovascular monitor (ICM) and implantable loop recorder (ILR) services are very different services and the PE cannot be appropriately captured for both services in a single technical code. They noted that CPT codes 93297–93299 will be placed on the new technology/new services list and be re-reviewed by the RUC in 3 years to ensure correct calculation and utilization assumptions. It was noted in the RUC recommendations that the specialty society intended to submit a coding proposal to the CPT Editorial Panel to delete CPT code 93299, as it will no longer be necessary to have a separate code for PE if CPT codes 93297 and 93298 are allocated direct PE in CY 2020.

In our review of these services, we noted that the RUC recommendations did not provide a detailed description of the clinical labor tasks being performed or detailed information on the typical use of the supply and equipment used when furnishing these services. These details are important in order for us to review if the RUC-recommended PE inputs are appropriate to furnish these services. The RUC submitted PE inputs (which were not previously included) for the work-only CPT codes 93297 and 93298, but did not include details to substantiate these recommended PE inputs for any of the three codes in this family.

Additionally, we were concerned with the appropriateness of the RUC's reference code, CPT code 93296 (*Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*). CPT code 93296 is for remote monitoring over a 90-day period, but was used as a reference to derive the RUC-recommended direct PE inputs for CPT codes 93297–93299, which are for remote monitoring over a 30-day period.

For the CY 2020 direct PE inputs, we proposed to remove the clinical labor time for ''Perform procedure/service—not directly related to physician work time'' (CA021); to remove the requested quantity for the supply ''Paper, laser printing (each sheet)'' (SK057); and to refine the equipment times in accordance with our standard equipment time formulas for CPT codes 93297 and 93298.

Although we did not propose to allocate direct PE inputs for CPT codes 93297 and 93298, we sought additional comment on the appropriateness of CPT code 93296 as the reference code, details on the clinical labor tasks, and more information on the typical use of the supply and equipment used to furnish these services. For example, it was unclear in the RUC recommendations how many patients are monitored concurrently. As an additional example, it was unclear in the RUC recommendations as to what tasks are involved when clinical staff engage with the patient throughout the month to perform education about the device and re-education protocols after the initial enrollment.

The CPT Editorial Panel is deleting CPT code 93299 for CY 2020. We note this differs from the RUC recommendations for this code from the October 2018 meeting, which stated that the specialty society intended to submit a coding proposal to the CPT Editorial Panel to delete CPT code 93299, as it would no longer be necessary to have a separate code for PE, if CPT codes 93297 and 93298 are allocated direct PE for CY 2020. Given that we proposed to not allocate direct PE inputs for CPT code 93297 and 93298 for CY 2020 and CPT code 93299 is being deleted for CY 2020, we proposed to create a G-code to describe the services previously furnished under CPT code 93299. We proposed to create HCPCS code G2066 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*), to describe the services previously furnished under CPT code 93299, effective for CY 2020.

We received public comments on the proposed valuation of the codes in the Remote Interrogation Device Evaluation family. The following is a summary of the comments we received and our responses.

Comment: One commenter stated strong support for CMS' proposal to not recommend the RUC recommended direct PE inputs for CPT codes 93297 and 93298, and to create a contractor-priced G-code to replace CPT code 93299, which has been eliminated by the AMA CPT. This commenter further noted that they understood the interest in creating nationally priced CPT codes that reflect the differences in expenses between ILR and ICM monitoring services, the agreed that the RUC recommendations, which were developed without input from IDTFs like theirs and are not substantiated and should not be implemented. They urged that any future revaluation of this code family provide for input by all providers IDTFs that perform the service.

Response: We thank the commenter for their support of our proposal.

Comment: A commenter stated they agreed with our proposal and recommended that they all be finalized including a proposal to establish HCPCS code G2066 effective January 1, 2020. The commenter stated that as a threshold matter, that the descriptors for CPT codes 93297 and 93298 were not changed. They still describe only the professional component (PC) and do not describe the TC. Without a change in descriptor, adding PE inputs to these professional codes is very confusing, especially to IDTFS, such as theirs, who are not allowed to bill for professional services.

Response: We thank the commenter for their support of our proposal.

Comment: A commenter noted they were perplexed that CMS stated the RUC recommendations did not provide a detailed description of the clinical

labor tasks being performed or detailed information on the typical use of the supply and equipment used when furnishing these services.

Response: We thank the commenter for the additional information. We note that while the RUC's recommendations contained some of the same information provided in the commenter's letter, it did not contain the same level of granularity provided in the commenter's letter. As an example, in our review of the time data, we note that both documents (RUC recommendations and commenter's letter) stated that over the course of a month a technologist interacts with the patient 1.63 times a month to process device-generated notifications for 17 minutes. However, the commenter's letter provided more details and noted that *if* a device generates an alert it will be communicated to the manufacturer's servers. This would imply that 17 minutes for this task is not always warranted, specifically if no alerts are communicated to the manufacturer's servers. This was unclear to us because the RUC recommendations did not contain the level of details as the commenter's letter.

Comment: One commenter noted that CMS sought additional information on the appropriateness of CPT code 93296 as the reference code. The commenter noted that the current recommendation uses CPT code 93296 as a simple reference code and suggested that it is appropriate because it is a similar service insofar as it is a remote interrogation of an electrophysiology device with similarities in terms of information workflow, but the recommended inputs are based on new data that was not available when the codes were last valued and the recommended PE inputs are in no way a crosswalk to the inputs of CPT code 93296.

Response: We appreciate the feedback, but continue to question the appropriateness of this crosswalk because 93299 is a service for up to 30 days and CPT code 93296 is for up to 90 days of remote monitoring.

Comment: Several commenters did not support our proposals, stating that CMS should allocate the RUC-recommended direct PE inputs for CPT codes 93297 and 93298, and that the creation of HCPCS code GTTT1 (G2066) is unnecessary since CPT code 93299 is being deleted by the CPT Editorial Panel for CY 2020.

Response: We disagree with the commenters that the creation of HCPCS code G2066 is unnecessary because, CPT code 93299 is being deleted for CY 2020. We reiterate that the RUC recommendations noted CPT code 93299 would be deleted *if* CMS allocated direct PE inputs for CPT codes 93297 and 93298 and that the specialty society intended to submit an application to the CPT Editorial Panel to have CPT code 93299. Further, it was noted in RUC recommendations that the RUC recommended that CPT code 93299 be referred to CPT for deletion. Thus, based on the information submitted to CMS, our understanding is that the intent to delete CPT code was predicated on CMS allocating direct PEs to CPT codes 93297 and 93298. There was no indication in the RUC recommendations that an application to delete CPT code 93299 had been submitted and that it would be deleted for CY 2020. Furthermore, CPT code 93299 was reviewed at the October 2018 RUC, and related recommendations provided to CMS. CMS did not propose to allocate direct PE for those codes, thus it was necessary to create a HCPCS code G2066) to describe the services previously furnished under CPT code 93299, effective for CY 2020.

After consideration of the public comments, we are finalizing our proposals for the codes in the Remote Interrogation Device Evaluation family.

(60) Duplex Scan Arterial Inflow-Venous Outflow (CPT Codes 93985 and 93986)

In September 2018, the CPT Editorial Panel recommended replacing one HCPCS code (G0365) with two new codes to describe the duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access for complete bilateral and unilateral study. We proposed the RUC-recommended work RVU of 0.80 for CPT code 93985 (*Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study*), as well as the RUC-recommended work RVU of 0.50 for CPT code 93986 (*Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study*).

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity from 4 minutes to 2 minutes for both codes in the family. Two minutes is the standard time for this clinical labor activity, and 2 minutes is also the time assigned for this activity in the reference code, CPT code 93990 (*Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)*). There was no rationale provided in the recommended materials indicating why this additional clinical labor time would be typical for the procedures, and therefore, we proposed to refine to the standard time of 2 minutes. We are also proposing to adjust the equipment times to conform to this change in the clinical labor time.

We received public comments on the proposed valuation of the codes in the Remote Interrogation Device Evaluation family. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposal of the RUC-recommended work RVU for both codes in the family. Two commenters also stated that they supported the proposed direct PE refinements.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Duplex Scan Arterial Inflow-Venous Outflow family as proposed.

(61) Myocardial Strain Imaging (CPT Code 93356)

The CPT Editorial Panel deleted one Category III code and created one new Category I add-on code CPT code 93356 to describe the work of myocardial strain imaging performed in supplement to transthoracic echocardiography services. We proposed the RUC-recommended work RVU of 0.24.

We proposed the RUC-recommended direct PE inputs for CPT code 93356. However, we note that no rationale was given for the RUC-recommended 12 minutes of clinical labor time for the activity CA021 ''Perform procedure/service,'' and we requested comment on the appropriateness of this allocated time value.

We received public comments on the proposed valuation of the codes in the Myocardial Strain Imaging family. The following is a summary of the comments we received and our responses.

Comment: A commenter supported our proposal to use the RUC-recommended work RVU for this code.

Response: We appreciate the support for our proposal from the commenters.

Comment: A commenter stated that, contrary to our statement that no rationale was provided for the times recommended for the ''perform procedure/service—NOT directly related to physician work time'' (CA021) clinical labor activity, the RUC had included detailed information on the RUC-recommended clinical labor in the PE SOR, and the commenter reiterated the rationale.

Response: We thank the commenter for the clarification.

After consideration of the public comments, we are finalizing our proposals for this code.

(62) Lung Function Test (CPT Code 94200)

The RUC recommended this service for survey because it appeared on a list of CMS/Other codes with Medicare utilization of 30,000 or more. According to the RUC, this service is typically reported with an E/M service and another pulmonary function test, and the RUC-recommended times would appropriately account for any overlap with other services. The RUC stated that the intraservice time involves reading and interpreting the test to determine if a significant interval change has occurred and then generating a report, which supports the 5 minutes of physician work indicated in the survey. The RUC did not agree with the specialty society that communication of the report required an additional 2 minutes of physician time over the postservice time included in the other services reported on the same day. The RUC reduced the postservice time from 2 minutes to 1 minute because the service requires minimal time to enter the results into the medical record and communicate the results to the patient and the referring physician. Based in part on these reductions in physician time, the RUC recommended a reduction in work RVU from the current value with a crosswalk to CPT code 95905 (*Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report*).

For CPT code 94200 (*Maximum breathing capacity, maximal voluntary ventilation*), we proposed the RUC-recommended work RVU of 0.05. A stakeholder stated that the RUC's recommended work RVU understates the costs inherent in performing this service, and that the survey 25th percentile value of 0.10 is more accurate for this service. While we proposed the RUC-recommended 0.05, we solicited public comment on this stakeholder-recommended potential alternative value.

We proposed the RUC-recommended direct PE inputs for CPT code 94200 without refinement.

We received public comments on the proposed valuation of the codes in the Lung Function Test family. The following is a summary of the comments we received and our responses.

Comment: A commenter questioned how the most recent stakeholder comment was obtained, since the RUC recommendations are not public until after the publication of the proposed rule. The commenter stated that the recent stakeholder comment could not have been received by CMS via the formal comment process, and questioned whether the comment was communicated via the passing of verbal comments between individuals at the RUC meeting or someone inappropriately gained confidential information.

Response: As noted for the Arthrodesis—Sacroiliac Joint code (CPT Code 27279), such communication between the agency and a stakeholder was not inappropriate. When considering potential valuation for services on the PFS, we may take into account information provided to us by stakeholders including specialty societies that may have participated in the RUC process but did not agree with what was submitted as part of the RUC's recommendations. For instance, in CY 2019 rulemaking, for the Psychological and Neuropsychological Testing family of codes, we noted that a stakeholder that represents the psychologist and neuropsychologist community stated that the RUC's recommendations for those services would have resulted in significant reductions in payment (FR 83 35770).

Comment: The RUC reiterated that it considered the survey 25th percentile, but ultimately decided that it would overvalue the work involved in performing this service given the survey intra-service time of 5 minutes, and they instead recommended a work RVU of 0.05.

Response: After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 0.05 as proposed. We are finalizing the direct PE inputs for CPT code 94200 as proposed.

(63) Long-Term EEG Monitoring (CPT Codes 95700, 95705, 95706, 95707, 95708, 95709, 95710, 95711, 95712, 95713, 95714, 95715, 95716, 95717, 95718, 95719, 95720, 95721, 95722, 95723, 95724, 95725, and 95726)

In January 2017, the RUC identified CPT code 95951 via the high volume growth screen, which considers if the service has total Medicare utilization of 10,000 or more and if utilization has increased by at least 100 percent from 2009 through 2014. The RUC recommended that this service be referred to the CPT Editorial Panel for needed changes, including code deletions, revision of code descriptors, and the addition of new codes to this family. In May 2018, the CPT Editorial Panel approved the revision of one code, deletion of five codes, and addition of 23 new codes for reporting long-term EEG professional and technical services. We are using the phrase ''professional component'' codes to refer to CPT codes 95717–95726 and ''technical component'' codes to refer to CPT codes 95700–95716.

We proposed the RUC-recommended work RVU for six of the professional component (PC) codes in this family. We proposed a work RVU of 3.86 for CPT code 95721 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 36 hours, up to 60 hours of EEG recording, without video*), a work RVU of 4.70 for CPT code 95722 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 36 hours, up to 60 hours of EEG recording, with video*), a work RVU of 4.75 for CPT code 95723 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 60 hours, up to 84 hours of EEG recording, without video*), a work RVU of 6.00 for CPT code 95724 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 60 hours, up to 84 hours of EEG recording, with video*), a work RVU of 5.40 for CPT code 95725 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 84 hours of EEG recording, without video*) and a work RVU of 7.58 for CPT code 95726 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 84 hours of EEG recording, with video*).

We also proposed adopting the RUC-recommended work RVU of 0.00 for the 13 technical component (TC) codes in the family: CPT code 95700 (*Electroencephalogram (EEG) continuous recording, with video when performed, set-up, patient education, and take down when performed, administered in-person by EEG technologist, minimum of 8 channels*), CPT code 95705 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, 2–12 hours; unmonitored*),

CPT code 95706 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, 2–12 hours; with intermittent monitoring and maintenance*), CPT code 95707 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, 2–12 hours; with continuous, real-time monitoring and maintenance*), CPT code 95708 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, each increment of 12–26 hours; unmonitored*), CPT code 95709 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, each increment of 12–26 hours; with intermittent monitoring and maintenance*), CPT code 95710 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, each increment of 12–26 hours; with continuous, real-time monitoring and maintenance*), CPT code 95711 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2–12 hours; unmonitored*), CPT code 95712 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2–12 hours; with intermittent monitoring and maintenance*), CPT code 95713 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2–12 hours; with continuous, real-time monitoring and maintenance*), CPT code 95714 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12–26 hours; unmonitored*), CPT code 95715 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12–26 hours; with intermittent monitoring and maintenance*), and CPT code 95716 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12–26 hours; with continuous, real-time monitoring and maintenance*).

We disagreed with the RUC-recommended work RVU of 2.00 for CPT code 95717 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, 2–12 hours of EEG recording; without video*) and we proposed a work RVU of 1.85 based on a crosswalk to CPT code 93314 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only*). CPT code 93314 is a recently-reviewed code with 2 additional minutes of intraservice time and 4 additional minutes of total time as compared to CPT code 95717. When considering the work RVU for CPT code 95717, we looked to the second reference code chosen by the survey participants, CPT code 95957 (*Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)*). This code has 2 additional minutes of intraservice time and 9 additional minutes of total time as compared to CPT code 95717, yet has a work RVU of 1.98, lower than the recommended work RVU of 2.00. These time values suggested that CPT code 95717 would be more accurately valued at a work RVU slightly below the 1.98 of CPT code 95957. We also looked at the intraservice time ratio between CPT code 95717 and some of its predecessor codes. The intraservice time ratio with CPT code 95953 (*Monitoring for localization of cerebral seizure focus by computerized portable 16 or more channel EEG, electroencephalographic (EEG) recording and interpretation, each 24 hours, unattended*) suggests a similar potential work RVU of 1.91 (28 minutes divided by 45 minutes times a work RVU of 3.08). Based on this information, we proposed a work RVU of 1.85 for CPT code 95717 based on the aforementioned crosswalk to CPT code 93314.

We disagreed with the RUC-recommended work RVU of 2.50 for CPT code 95718 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and report, 2–12 hours of EEG recording; with video (VEEG)*) and we proposed a work RVU of 2.35. Although we disagreed with the RUC-recommended work RVU, we concurred with the RUC that the relative difference in work between CPT codes 95717 and 95718 is equivalent to the recommended interval of 0.50 RVUs. Therefore, we proposed a work RVU of 2.35 for CPT code 95718, based on the recommended interval of 0.50 additional RVUs above our proposed work RVU of 1.85 for CPT code 95717. We supported this work RVU with a reference to CPT code 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of the 3 key components*), which shares the same intraservice time of 35 minutes and the identical work RVU of 2.35. CPT code 99310 is a lower intensity procedure but has increased total work time as compared to CPT code 95718.

We disagreed with the RUC-recommended work RVU of 3.00 for CPT code 95719 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; without video*), and we proposed a work RVU of 2.60 based on a crosswalk to CPT code 99219 (*Initial observation care, per day, for the evaluation and management of a patient, which requires 3 key components*). CPT code 99219 shares the same intraservice time of 40 minutes and has a slightly higher total time as compared to CPT code 95719. We also noted that the observation care described by CPT code 99219 shares some clinical similarities to the long term EEG monitoring described by CPT code 95719, although we noted, as always, that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another, and that codes do not need to share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

In addition, we believed that the proposed crosswalk to CPT code 99219 at a work RVU of 2.60 more accurately captures the intensity of CPT code 95719. At the recommended work RVU of 3.00, the intensity of CPT code 95719 is anomalously high in comparison to the rest of the family, higher than any of the other PC codes. We did not have reason to believe that the 24-hour EEG monitoring done without video, as described in CPT code 95719, would be notably more intense than the other codes in the same family. Furthermore, the recommendations for this code family specifically state that the codes that describe video EEG monitoring are more intense than the codes that describe non-video EEG monitoring. However, at the recommended work RVU for CPT code 95719, this non-video form of EEG monitoring had the highest intensity in the family. At our proposed work RVU of 2.60, the intensity of CPT code 95719 is no longer anomalously high in comparison to the rest of the family, and also remains lower than the intensity of the 24 hour EEG monitoring with video procedure described by CPT code 95720.

We disagreed with the RUC-recommended work RVU of 3.86 for CPT code 95720 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; with video (VEEG)*), and we proposed a work RVU of 3.50 based on the survey 25th percentile value. The RUC-recommended work RVU of 3.86 was based on a crosswalk to CPT code 99223 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires 3 key components*), a code that shares the same intraservice time of 55 minutes but has 15 additional minutes of total time as compared to CPT code 95720, at 90 minutes as compared to 75 minutes. We disagreed with the use of this crosswalk, as the 15 minutes of additional total time in CPT code 99223 resulted in a higher work valuation that overstates the work RVU of CPT code 95720. These 15 additional minutes of preservice and postservice work time in the recommended crosswalk code have a calculated work RVU of 0.34 under the building block methodology; subtracting out this work RVU of 0.34 from the crosswalk code's work RVU of 3.86 resulted in an estimated work RVU of 3.52, which is nearly identical to the survey 25th percentile work RVU of 3.50. Similarly, if we were to calculate a total time ratio between CPT code 95720 and the recommended crosswalk code 99223, it would produce a noticeably lower work RVU of 3.22 (75 minutes divided by 90 minutes times a work RVU of 3.86). Based on this rationale, we did not believe that it would serve the interests of relativity to propose a work RVU of 3.86 based on the recommended crosswalk.

Instead, we proposed a work RVU of 3.50 for CPT code 95720 based on the survey 25th percentile value. We noted that among the predecessor codes for this family, CPT code 95956 (*Monitoring for localization of cerebral seizure focus by cable or radio, 16 or more channel telemetry, electroencephalographic (EEG) recording and interpretation, each 24 hours, attended by a technologist or nurse*) had a higher intraservice time of 60 minutes and a higher total time of 105 minutes at a work RVU of 3.61. This prior valuation of CPT code 95956 does not support the RUC-recommended work RVU of 3.86 for CPT code 95720, but does support the proposed work RVU of 3.50 at the slightly lower newly surveyed work times. We also noted that at the recommended work RVU of 3.86, the intensity of CPT code 95720 was anomalously high in comparison to the rest of the family, the second-highest intensity as compared to the other PC codes. We did not have reason to believe that the 24 hour EEG monitoring done with video as described in CPT code 95720 would be notably more intense than the other codes in the same family. At our proposed work RVU of 3.50, the intensity of CPT code 95720 is no longer anomalously high in comparison to the rest of the family, while still remaining slightly higher than the intensity of the 24 hour EEG monitoring performed without video procedure described by CPT code 95719.

For the direct PE inputs, we proposed to make a series of refinements to the clinical labor times of CPT code 95700. Many of the clinical labor times for this CPT code were derived using a survey process and were recommended to CMS at the survey median values. This was in contrast to the typical process that the RUC uses to make recommendations for direct PE inputs, where the inputs are usually based on either standard times or carried over from reference codes. We believe that when surveys are used to recommended direct PE inputs, we must apply a similar process of scrutiny to that used in assessing the work RVUs that are recommended based on a survey methodology. We have long expressed our concerns over the validity of the survey results used to produce work RVU recommendations, such as in the CY 2011 PFS final rule (75 FR 73328), and we have noted that over the past decade the AMA RUC has increasingly chosen to recommend the survey 25th percentile work RVU over the survey median value, potentially responding to the same concerns that we have identified.

As a result, we believe that when assessing the survey of direct PE inputs used to produce many of the recommendations for CPT code 95700, it would be more accurate to propose the survey 25th percentile direct PE inputs as opposed to the recommended survey median direct PE inputs. Therefore, we proposed to refine the clinical labor time for the ''Provide education/obtain consent'' (CA011) activity from 13 minutes to 7 minutes and to refine the clinical labor time for the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) activity from 10 minutes to 7 minutes. In both of these cases, the recommended clinical labor times based on the survey median values are more than double the standard time for these activities. Although we agreed that additional clinical labor time would be required to carry out these activities for CPT code 95700, we did not believe that the survey median times would be typical. We proposed the survey 25th percentile times of 7 minutes for each activity as we believe that this time would be more typical for obtaining consent and reviewing home care instructions.

We also proposed to refine the clinical labor time for the ''Complete pre-procedure phone calls and prescription'' (CA005) activity from 10 minutes to 3 minutes for CPT code 95700. This is another situation where we proposed the survey 25th percentile clinical labor time of 3 minutes instead of the survey median clinical labor time of 10 minutes. However, we also note that many of the tasks that fell under the CA005 activity code as described in the PE recommendations appear to constitute forms of indirect PE, such as collecting supplies for setup and loading equipment and supplies into vehicles. Collecting supplies and loading equipment are administrative tasks that are not individually allocable to a particular patient for a particular service, and therefore, constitute indirect PE under our methodology. Due to the fact that many of the tasks described under the CA005 activity code are forms of indirect PE, we believed that the RUC-recommended survey median clinical labor time of 10 minutes overstated the amount of direct clinical labor taking place. We believed that it was more accurate to propose the survey 25th percentile clinical labor time of 3 minutes for this activity code to reflect the non-administrative tasks performed by the clinical staff.

We also proposed to refine the quantity of the non-sterile gloves (SB022) supply from 3 to 2 for CPT code 95700. We note that the current reference code, CPT code 95953, uses 2 of these pairs of gloves and the survey also stated that 2 pairs of gloves were typical for the procedure. Although the recommended materials state that a pair of gloves is needed to set up the equipment, to take down the equipment, and a third is required for electrode changes, we did not agree that the use of a third pair of gloves would be typical given their usage in the reference code and in the responses from the survey.

We note that we did not propose to refine many of the other clinical labor times for CPT code 95700, which remain at the survey median clinical labor times. Due to the nature of the continuous recording EEG service taking place, we agree that the survey median clinical labor times of 12 minutes for the ''Prepare room, equipment and supplies'' (CA013) activity, 45 minutes

for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity, and 22 minutes for the ''Clean room/equipment by clinical staff'' (CA024) activity would be typical for this procedure. We reiterate that we assess the direct PE inputs for each procedure individually based on our methodology of what would be reasonable and medically necessary for the typical patient.

For CPT codes 95705–95716, we proposed to refine the clinical labor time for the ''Coordinate post-procedure services'' (CA038) activity from either 11 minutes to 5 minutes or from 22 minutes to 10 minutes as appropriate for the CPT code in question. The recommended materials for these procedures state that the tasks taking place constitute ''Merge EEG and Video files (partially automated program), confirm transfer of data, delete from laptop/computer if necessary''. We believe that many of the tasks detailed here are administrative in nature, consisting of forms of data entry, and therefore, would be considered types of indirect PE. We note that when CPT code 95812 (*Electroencephalogram (EEG) extended monitoring; 41–60 minutes*) was recently reviewed for CY 2017, we finalized the recommended clinical labor time of 2 minutes for ''Transfer data to reading station & archive data'', a task which we believe to be highly similar. Due to the longer duration of the procedures in CPT codes 95705–95716, we proposed clinical labor times of 5 minutes and 10 minutes for the CA038 activity for these CPT codes. We are also refining the equipment time for the Technologist PACS workstation (ED050) to match the clinical labor time proposed for the CA038 activity.

For the four continuous monitoring procedures, CPT codes 95707, 95710, 95713, and 95716, we proposed to refine the equipment time for the ambulatory EEG review station (EQ016) equipment. The recommended equipment time for the ambulatory EEG review station was equal to four times the ''Perform procedure/service'' (CA021) clinical labor time plus a small amount of extra prep time. We did not agree that it would be typical to assign this much equipment time, as it is our understanding that one ambulatory EEG review station can be hooked up to as many as four monitors at a time for continuous monitoring. Therefore, we did not believe that each monitor would require its own review station, and therefore, the equipment time should not be equal to four times the clinical labor of the ''Perform procedure/service'' (CA021) activity. As a result, we proposed to refine the ambulatory EEG review station equipment time from 510 minutes to 150 minutes for CPT code 95707, from 1480 minutes to 400 minutes for CPT code 95710, from 514 minutes to 154 minutes for CPT code 95713, and from 1495 minutes to 415 minutes for CPT code 95716.

For the 10 professional component procedures, CPT codes 95717–95726, we again proposed to refine the equipment time for the ambulatory EEG review station (EQ016) equipment. We believe that the use of the ambulatory EEG review station is analogous in these procedures to the use of the professional PACS workstation (ED053) in other procedures, and we proposed to refine the equipment times for these 10 procedures to match our standard equipment time formula for the professional PACS workstation. Therefore, we proposed an equipment time for the ambulatory EEG review station equal to half the preservice work time (rounded up) plus the intraservice work time for CPT codes 95717 through 95726. We believed that this equipment time was more accurate than the recommended equipment time, which was equal to the total work time of the procedures, as the work descriptors for CPT codes 95717–95726 make no mention of the ambulatory EEG review station in the postservice work period.

Finally, we proposed to price the new ''EEG, digital, prolonged testing system with remote video, for patient home use'' (EQ394) equipment at $26,410.95 based on an invoice submission. We did not use a second invoice submitted for the new equipment for pricing, as it contained a disaggregated list of equipment components and it was not clear if they represented the same equipment item as the first invoice.

We received public comments on the proposed valuation of the codes in the Long-Term EEG Monitoring family. The following is a summary of the comments we received and our responses. Due to the large number of comments we received for this code family, we will first summarize the comments related to general code valuation, followed by the comments related to specific work RVUs, and finally the comments related to direct PE inputs.

Comment: Many commenters expressed concern with the proposed values for the codes in the Long Term EEG Monitoring family. Commenters stated that the proposed values would jeopardize beneficiary access to these tests, which are vitally important to patients with epilepsy and other seizure disorders. Commenters listed some of the benefits resulting from advances in technology that now make it possible for patients to receive long-term EEGs in their home, particularly for patients in rural and medically underserved communities. Commenters stated that if the proposed values were finalized, many Medicare beneficiaries will be forced to be admitted to a hospital to receive the same testing they could have received in their home, driving up costs to both the beneficiary and the federal government. These commenters requested that CMS withdraw the proposed reductions in values for in-home EEG tests and continue paying at rates established by regional Medicare Administrative Contractors (MACs) in their respective jurisdictions. Commenters stated that CMS has taken this approach in the past for services such as the Transcranial Magnetic Stimulation family (CPT codes 90867, 90868, 90869), which do not fit into the standard valuation methodology, and that continuing to use contractor pricing for a period of 3 to 4 years would allow health care providers and MACs to gain experience with the new codes.

Response: We appreciate the feedback from the commenters on the importance of maintaining access to these services. We agree with the commenters that it is critical for payment for services furnished to Medicare beneficiaries be accurately valued, and we share their desire to ensure that patients in rural and medically underserved communities will continue to receive care, especially in light of the rapidly growing utilization of EEG monitoring procedures. These services were flagged for review due to a high volume growth screen, which considers if the service has total Medicare utilization of 10,000 or more and if utilization has increased by at least 100 percent from 2009 through 2014. Based on the identification of these services in the high volume growth screen, the CPT Editorial Panel updated the coding by revising code descriptions, deleting codes, and adding new codes, with the goal of incorporating the current use of video in EEG tests, better differentiating inpatient and ambulatory monitoring services, and reflecting the rapid increase in utilization for these services.

We estimate that utilization for the new Long Term EEG Monitoring code set will exceed 500,000 services annually in CY 2020, and, generally speaking, we believe it is more accurate for the purposes of relativity to establish national pricing for services that will have high utilization as opposed to leaving them contractor-priced. However, we have carefully considered commenters' concerns regarding the accuracy of the proposed inputs, especially in the context of the

accessibility and payment stability concerns also raised by the commenters, and we have decided that the proposed payment for the TC Long Term EEG Monitoring codes (CPT codes 95700–95716) should be withdrawn in favor of contactor-pricing for CY 2020 in order to allow additional time for stakeholder feedback. We are seeking additional information from stakeholders that will address the concerns about the resource inputs involved in furnishing these services in the context of the accessibility and need for payment stability raised by the commenters. We will further consider establishing national values for these codes through future rulemaking.

Comment: Several commenters stated that the PE methodology CMS used to establish values for TC services was inappropriate for these codes, and the recommendations from the RUC for PE inputs were so flawed as to be unusable. Commenters stated that the PE information submitted by the RUC to CMS was deeply flawed, as it was collected from physicians and EEG technologists who are employed by hospitals or physician offices and unfamiliar with home studies. Several commenters stated that the RUC recommendations did not include as PE inputs the significant fees for software, data usage, and cell phones which are necessary to establish and maintain the monitoring connections in the patient's home. Commenters also stated that the RUC-recommended work times were not reasonable for these procedures, as practitioners needed to go through video data and patient logs, as well as type up a detailed report and review patient history. Some commenters were critical of the RUC's survey methodology, stating that the work surveys were biased or flawed and suffered from a low response rate. Commenters stated that surveys are notoriously inaccurate and physicians rarely if ever use surveys to determine patients' care due to biases that result from a low response rate. These commenters were critical of the RUC's survey methodology in general and stated that the relatively small number of survey respondents were not representative of wider practice patterns.

Response: We appreciate the feedback from the commenters regarding the work RVUs, work times, and direct PE inputs recommended by the RUC. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches that we use to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation. We emphasize that we do not believe that the RUC is the exclusive source of information used in valuation of PFS services, and we are supportive of the submission of additional data that can aid in the process of determining the resources that are typically used to furnish these services. However, in the absence of alternative data to value new services, we believe that the recommendations from the RUC are a key source to use for valuation of work and direct PE, and therefore, these recommendations have an important role in our review process and in our responsibility to assign relative value units used to determine payment rates under the PFS. Because we did not receive data from the commenters to support alternate valuations from the RUC recommendations, not only do we believe it is appropriate to consider the RUC recommendations, we do not believe it would be appropriate to ignore the RUC recommendations for work RVUs and direct PE inputs for the Long Term EEG Monitoring family of codes. However, we urge interested stakeholders to consider submitting robust data regarding direct PE resource inputs and costs involved in furnishing these and other services for our consideration for future rulemaking.

Comment: Several commenters acknowledged that there has been an increase (greater than 100 percent) in EEG utilization from 2009–2014, and stated that it was critical for CMS to study why this increase has occurred. Commenters stated that utilization has increased for these services due to the effect of the Affordable Care Act on epilepsy care, the increased need for EEG monitoring in the ICU, the importance of long-term monitoring for accurate diagnoses for patients with seizures, and due to the presence of outlier cases. Commenters stated that millions of patients have obtained insurance over the last few years and many of the previously uninsured were poor and lower income, and therefore, the population of newly insured patients with psychiatric diagnoses has increased. Commenters stated that an abundance of data has emerged over the last 10 years demonstrating that more intensive continuous EEG monitoring in the ICU is needed to detect seizures that the prevalence of seizures that were previously undetected is very high in critically ill patients, and that patients with untreated seizures and non-convulsive status epilepticus have significantly poorer outcomes. Commenters stated that if physicians truly were able to more efficiently interpret EEG, this increased efficiency would not be a reasonable justification for changing payment. Commenters stated that if a worker is more productive most businesses would encourage this, and the worker would not be punished for more efficient work.

Response: We appreciate the additional information supplied by the commenters regarding the potential causes behind increasing utilization of these services. We note that while observed increases in utilization contributed to review of these services under the misvalued code initiative, we establish RVUs based on the resources involved in furnishing services. We remind commenters that section 1848(c)(2)(C)(i) of the Act specifically defines the work component as the relative resources, incorporating time and intensity, required in furnishing the service. As such, if the work time for a service has decreased as a result of improvements in technology or practice patterns, those things should be reflected in the work valuation.

Comment: Several commenters stated that there were potential rank order anomalies in the proposed valuation of the codes in this family. Commenters stated that the TC of CPT code 95819 (*Electroencephalogram (EEG); including recording awake and asleep*), considered a routine EEG of 20–40 minutes recording, was valued higher than several of the new Long Term EEG Monitoring codes, including CPT codes 95711, 95712, 95714, 95708, and 95706. Commenters also stated that CPT code 95710, which does not include video, was valued higher than CPT code 95716, which does include video. Commenters questioned why the more resource intensive service with video would be valued less than the same service without video.

Response: We do not agree with the commenters that the identified codes represent rank order anomalies. CPT code 95819 has significantly more clinical labor time (154 minutes) than CPT codes 95711, 95712, 95714, 95708, and 95706. We remind readers that this is due to the fact that the new TC Long Term EEG Monitoring codes do not include direct PE inputs for setting up or taking down the monitoring equipment, which are separately reported under CPT code 95700. These direct PE inputs associated with setup and takedown are included in CPT code 95819, which, along with its greater assignment of clinical labor time, explains why it has a higher valuation that these procedures.

With regard to CPT codes 95710 and 95716, we agree that, generally speaking, the version of the procedure

that includes video would be valued higher than the version of the procedure that does not include video. We note that this is the pattern for all of the other video/non-video pairings in this code family, such as CPT codes 95705 and 95711, CPT codes 95706 and 95712, CPT codes 95707 and 95713, CPT codes 95708 and 95714, and CPT codes 95709 and 95715. We also note that the proposed direct costs for CPT code 95710 are lower than the proposed direct costs for CPT code 95716. However, the total payment rate referred to by the commenter (that is, the total sum RVU for these codes) also includes the indirect PE portion of the payment and, under our ratesetting methodology, CPT code 95710 received a slightly higher indirect PE allocation as compared to CPT code 95716. This was due to the different utilization crosswalks that we proposed for the two codes, in which CPT code 95710 was crosswalked from services that would currently be reported using CPT code 95953 while CPT code 95716 was crosswalked from services that would currently be reported using CPT code 95951. Because CPT code 95953 has a slightly higher indirect PE allocation as compared to CPT code 95951, under the proposed new coding for CY 2020, CPT code 95710 would also have a slightly higher indirect PE allocation and receive slightly more indirect PE in comparison to CPT code 95716. We remind readers that indirect PE makes up a significant amount of the PE RVUs and, as such, the total payment for services; and procedures with greater direct PE costs do not always have a larger PE RVU. We also note that the proposed differential between these two new CPT codes was one half of one percent, which we do not believe to be a statistically significant amount, and that all of the TC codes in this family will be contractor-priced for CY 2020.

Comment: Several commenters stated that the phase-in of significant relative value unit reductions applies to codes that are not new or revised, which would exclude the long-term EEG monitoring codes. However, commenters still urged CMS to apply the phase-in to this family of codes due to the proposed payment reductions.

Response: Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. We did not propose to apply the phase-in of significant RVU reductions required by section 1848(c)(7) of the Act to the codes in the Long Term EEG Monitoring family due to the fact that they are all new codes created by the CPT Editorial Panel, which are statutorily excluded from the phase-in provision. For additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70929).

Comment: Several commenters stated that the primary issues related to the undervaluation of the 2–12 hour EEG TC services (CPT codes 95705–95707 and 95711–95713) appeared to be a result of a misunderstanding of where and how these services are provided. Commenters stated that these codes were valued as if they typically will be performed in a physician's office setting, when in fact EEG TC services are typically performed in the home setting regardless of duration. Commenters stated that the proposed valuation was fatally flawed as a result, and stated that CMS should refrain from finalizing the proposed valuation and temporarily authorize contractor pricing pending revaluation that takes into consideration data to be provided from IDTFs.

Response: We disagree with the commenters that the 2–12 hour EEG TC codes would typically be performed in the home setting regardless of duration. The RUC reviewed and developed recommendations for these codes with the understanding that they were typically performed in the office setting. We emphasize that we do not believe that the RUC is the exclusive source of information used in valuation of PFS services, and we are supportive of the submission of additional data that can aid in the process of determining the resources that are typically used to furnish these services. However, in the absence of alternative data used to value new services, we believe that the recommendations from the RUC, generally speaking, are the most accurate source to use when it comes to determining the typical site of service for new codes. Because we did not receive data from the commenters to support their contention that the patient's home would be the typical setting for these codes, we do not believe that it would be appropriate to ignore the RUC recommendations regarding the related direct PE inputs. However, we urge interested stakeholders to consider submitting robust data regarding site of service for these and other services.

The following comments address the proposed work valuation of individual codes in the family.

Comment: Several commenters stated that the PC codes in the family (CPT codes 95717–95726) should be viewed as two distinct subsets when considering rank order for the family, as they represent two distinct patient populations. Commenters stated that when viewing the family of codes in this manner, the RUC-recommended work RVUs do not create a rank order anomaly for the family and recognize both the time and intensity of the services. Commenters stated that CPT codes 95717–95720 are typically facility-based services, provided to hospital inpatients and outpatients, in which the work is more complex and intense as the typical patients are undergoing pre-surgical evaluations and/or being withdrawn from anti-seizure medications to induce seizures. Commenters stated that CPT codes 95721–95726 will be provided to patients primarily tested in their homes, in which the practitioner does not access the data until the conclusion of the study. Commenters urged CMS to accept the RUC-recommended work RVUs for all of these PC codes.

Response: We disagree with the commenters that the PC codes in the family (CPT codes 95717–95726) should be viewed as two distinct subsets when considering rank order for the family. We believe that all ten of these new codes were created together by the CPT Editorial Panel, surveyed together by the specialty societies, and reviewed together by the RUC. We do not believe that it would serve the purpose of maintaining relativity to consider the first four codes separate from the last six codes, any more than it would be appropriate to consider only the video or only the non-video codes separate from their counterparts. We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate basis of comparison.

Comment: Many commenters disagreed with the CMS proposed work RVU of 1.85 for CPT code 95717 and stated that CMS should instead finalize the RUC-recommended work RVU of 2.00. Commenters stated that the CMS crosswalk code (CPT code 93314) was a poor reference point in general, as CMS finalized a work RVU for this crosswalk

code much lower than its RUC-recommended value of 2.80. Commenters also stated that the proposed work RVU of 1.85 would not maintain appropriate relativity to other services in this family, particularly CPT code 95813 (*Electroencephalogram (EEG) extended monitoring; 61–119 minutes*), for which CMS finalized the RUC-recommended work RVU of 1.63 in CY 2018. Commenters stated that the proposed value would inappropriately assign CPT code 95717 an intensity that is 10 percent lower than CPT code 95813.

Response: We appreciate the additional information provided by the commenters with respect to CPT code 95813. Based on the information provided by the commenters, we are not finalizing our proposed work RVU of 1.85, and we will instead finalize the RUC-recommended work RVU of 2.00 for CPT code 95717.

Comment: Many commenters disagreed with the CMS-proposed work RVU of 2.35 for CPT code 95718 and stated that CMS should instead finalize the RUC-recommended work RVU of 2.50. Commenters stated that since the CMS rationale for rejecting the RUC recommendation for CPT code 95717 was flawed as described above, it should not be used as the basis to derive a new value for CPT code 95718. Commenters stated that the CMS reference code (CPT code 99310) was a poor comparator as it is typically performed by a nonphysician and involves highly disparate work. Commenters stated that the proposed value would not maintain appropriate relativity to other services in this family, particularly CPT code 95813, by inappropriately assigning CPT code 95718 a lower intensity.

Response: As we stated in the proposed rule, we concurred with the RUC that the relative difference in work between CPT codes 95717 and 95718 is equivalent to the recommended interval of 0.50 RVUs. Since we are finalizing the RUC-recommended work RVU of 2.00 for CPT code 95717 based on feedback from commenters, we will also finalize the RUC-recommended work RVU of 2.50 for CPT code 95718 to maintain this incremental difference between the two codes.

Comment: Many commenters disagreed with the CMS proposed work RVU of 2.60 for CPT code 95719 and stated that CMS should instead finalize the RUC-recommended work RVU of 3.00. Commenters stated that the proposed crosswalk code (CPT code 99219) was inappropriate as observation care involves relatively less intensity than the typical long-term EEG described by the survey code. Commenters stated that although both services involve identical intraservice time and similar total time, CPT code 95719 is a more intense service performed on a sicker patient population. Commenters also stated that the proposed value would not maintain appropriate relativity to other services in this family, particularly CPT code 95813, by inappropriately assigning CPT code 95719 a lower intensity.

Response: We appreciate the additional information provided by the commenters with respect to CPT code 95813. Based on the information provided by the commenters, we are not finalizing our proposed work RVU of 2.60, and we will instead finalize the RUC-recommended work RVU of 3.00 for CPT code 95719.

Comment: Many commenters disagreed with the CMS proposed work RVU of 3.50 for CPT code 95720 and stated that CMS should instead finalize the RUC-recommended work RVU of 3.86. Commenters stated that CMS incorrectly referenced CPT code 95956 as a predecessor code for CPT code 95720, rather than CPT code 95951. Commenters stated that CPT code 95956 is the predecessor code for CPT code 95719, which has no video recording, and therefore, has a lower work RVU. Commenters stated that CMS appreciated the difference in work when video is recorded but used the wrong predecessor code for CPT code 95720.

Response: We disagree with the commenters that we referred to an incorrect predecessor code for CPT code 95720 in the proposed rule. We noted in the proposed rule that *among the predecessor codes for this family,* CPT code 95956 had a higher intraservice time of 60 minutes and a higher total time of 105 minutes at a work RVU of 3.61. We did not state that CPT code 95956 was a direct predecessor code for CPT 95720, as we were aware that it did not include video recording, and therefore, we did not include CPT code 95956 in the proposed utilization crosswalk for CPT code 95720. We continue to believe that it is appropriate to make comparisons between the codes that are currently used to report Long Term EEG Monitoring and the newly created codes that will be used for these services going forward.

Comment: Commenters also disagreed with the CMS criticism of the RUC-recommended crosswalk to CPT code 99223. Commenters stated that CMS seemed to be asserting that all crosswalks must have near identical work intensity instead of simply involving the same overall amount of work. Commenters stated that crosswalks with near identical times do not always exist, which was the case for this service, which sometimes necessitates selecting a crosswalk with somewhat disparate total time which has a different level of work intensity though the same overall amount of work. Commenters stated that although CPT code 99223 involved more total time, CPT code 95720 is a more intense service to perform given the difficulty involved in making an appropriate reading/diagnosis and a more intensive patient population in which the typical patient is a candidate for epilepsy surgery.

Response: We agree with the commenters that codes selected as crosswalks do not necessarily need to share the identical work times. However, since we are we are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services, we believe that, generally speaking, it is more accurate to use codes with similar work time values when determining which codes should be used for crosswalks. In the particular case of CPT code 95720, we believed that the 15 minutes of additional total time in CPT code 99223 as compared to CPT code 95720 resulted in a higher work valuation that overstated the work RVU of CPT code 95720.

Comment: Commenters also stated that the proposed work RVU for CPT code 95720 would not maintain appropriate relativity to other services in this family, particularly CPT code 95813, by inappropriately assigning CPT code 95720 a lower intensity. Commenters disagreed with the proposed work valuation of CPT code 95720 and stated that this code would indeed be notably more intense than the other codes in the same family given that the typical patient for that code is a candidate for epilepsy surgery. Commenters stated that CMS failed to take account for the typical patient for this service in determining the work valuation.

Response: We appreciate the additional information provided by the commenters with respect to CPT code 95813 and the typical patients for this code. Based on the information provided by the commenters, we are not finalizing our proposed work RVU of 3.50, and we will instead finalize the RUC-recommended work RVU of 3.86 for CPT code 95720. Therefore, we are finalizing the RUC-recommended work RVU for all ten of the PC codes in this family.

The following comments address the proposed direct PE inputs for the Long Term EEG Monitoring family of codes.

Comment: Many commenters were concerned that the RVUs associated with the TC Long Term EEG Monitoring services (CPT codes 95700–95716) would be reduced substantially from their predecessor codes, specifically as compared to CPT code 95951 and 95956. Commenters stated that these reductions would be unsustainable for these technical services, as the proposed values and resulting payment rates simply would not cover the costs.

Response: We are aware of the concerns raised by the commenters about the proposed values, and, as mentioned previously, we are finalizing contractor pricing for the TC Long Term EEG Monitoring services (CPT codes 95700–95716). Due to the high utilization of these services, we believe that they should eventually be transitioned to national pricing and, therefore, we are detailing and responding to many of the issues raised by stakeholders that relate to valuation of the TC codes. We believe that this discussion will assist in the eventual national pricing of these services through further rulemaking.

We note that there were many significant changes made to this code family when the previous Long Term EEG Monitoring codes were deleted and replaced with new codes, and we believe that it is important to explain for the commenters why the new TC codes do not correspond directly to the previous coding. Services will be reported differently under the new coding, and therefore, direct RVU comparisons between the old codes and the new codes are not necessarily accurate.

We note for readers that the new coding has been split into separate TC-only codes (CPT codes 95700–95716) and PC-only codes (CPT codes 95717–95726). Comparisons to the global component of the prior codes for Long Term EEG Monitoring, which included both PCs and TCs, would not be accurate due to this different coding structure. We also note that the new TC-only codes include a separate code for setting up and taking down the EEG equipment (CPT code 95700), whereas the prior coding contained these steps along with the monitoring itself in a single code. The new monitoring codes must be considered together with the setup code 95700 to be comparable to the previous coding.

We also believe that it is important to note that the new coding is more granular than the previous coding, and includes separate codes for 2–12 hours of monitoring (8 hours typical) along with codes for 12–26 hours of monitoring (24 hours typical). The previous codes only described Long Term EEG Monitoring in 24 hour increments, and it is natural to assume that the resources associated with providing 8 hours of monitoring would be less than those associated with 24 hours of monitoring. Many commenters compared the RVUs for new TC codes such as CPT codes 95712 and 95713, which have 8 hours of monitoring in the typical case, to CPT code 95951, which assumes 24 hours of monitoring is typical. The PE methodology under the PFS is a resource-based system, and if the typical case for some of the new TC services involves 8 hours of monitoring, we believe that this should be reflected in the RVUs for those services.

We note as well that the coding has become more granular in describing different types of monitoring. The prior Long Term EEG Monitoring coding only made a distinction between attended versus unattended monitoring, whereas the new coding includes a third category for intermittent monitoring. We would expect the RVUs for CPT codes 95706, 95709, 95712, and 95715 to decrease as compared to the prior coding that assumed monitoring would be continuous throughout the duration of the procedures.

Finally, we also note that changes in practice patterns for these services has affected them since their last time of review. CPT code 95956 (*Monitoring for localization of cerebral seizure focus by cable or radio, 16 or more channel telemetry, electroencephalographic (EEG) recording and interpretation, each 24 hours, attended by a technologist or nurse*) contained 1440 minutes of clinical labor time (24 hours times 60 minutes) associated with monitoring in its direct PE inputs, assuming that the patient would be individually monitored for the entirety of the 24 hour period. However, based on the recommendations from the RUC, we understand that it is now typical for the clinical labor technician to monitor 4 patients at a time, even during the continuous monitoring procedures. This is reflected in the recommended clinical labor inputs for CPT codes 95710 and 95716, which contain 360 minutes of clinical labor (1,440 divided by 4) instead of the 1,440 minutes in the previous coding. The shorter duration continuous monitoring codes similarly contain 120 minutes (8 hours times 60 minutes divided by 4) of clinical labor time to reflect the fact that monitoring 4 patients at a time is the typical practice, and the intermittent monitoring codes contain even less clinical labor time to reflect the fact that monitoring 12 patients at a time is typical practice. (Obviously the unattended monitoring codes do not contain any clinical labor at all for this activity as there is no technician monitoring the patient in these cases.)

The net result is that there is significantly less clinical labor associated with the new Long Term EEG Monitoring codes as compared to the prior coding set, and this was reflected in their proposed payment rates. We believe that it is important to propose the most accurate values possible under our relative value system, and if it has become the typical practice pattern for the technician to monitor 4 patients at a time, we believe that this should be reflected in the RVUs for these services. We do not believe that it would be accurate or serve the interests of relativity to continue to assign the prior 1,440 minutes of clinical labor time for the new TC codes if this no longer reflects current monitoring practice patterns. We emphasize again that we are finalizing contractor pricing for the TC codes, but we believe that if we were to adopt active pricing, the valuation must be resource-based and grounded in current practice patterns.

Comment: Several commenters disagreed with the CMS proposal of the survey 25th percentile direct PE inputs as opposed to the recommended survey median direct PE inputs for CPT code 95700. Commenters stated that the 25th percentile clinical labor times are a completely different measure than the 25th percentile work RVU, and the RUC makes recommendations on direct PE inputs only, not the PE RVUs which would be the equivalent of the work RVUs. Commenters also stated that the median survey times for work are what is most commonly recommended by the RUC, not the 25th percentile survey work times, which was even more reason to employ the survey median times from the PE survey. Commenters stated that PE surveys are especially difficult to conduct and require a great deal of resources from the specialty societies involved, and the commenters encouraged CMS to finalize the RUC-recommended direct PE inputs for CPT code 95700.

Response: We appreciate the feedback from the commenters regarding the use of the direct PE survey employed for CPT code 95700. We concur with the commenters that the use of a survey methodology to determine direct PE inputs is not identical to the surveys used for work valuation, which is why we stated in the proposed rule that we believed in applying ''a similar process of scrutiny'' and not the same process. We remind the commenters that we did not propose the 25th percentile value for all of the direct PE inputs, instead

choosing the survey value for each input that we believed to be most accurate based on the information that we had available. For example, we agreed in the proposed rule that the survey median clinical labor times of 12 minutes for the ''Prepare room, equipment and supplies'' (CA013) activity, 45 minutes for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity, and 22 minutes for the ''Clean room/equipment by clinical staff'' (CA024) activity would be typical for CPT code 95700. We believe that proposing the survey median value from the direct PE survey in all cases would be no more accurate than proposing the survey 25th percentile value in all cases. We reiterate that we assess the direct PE inputs for each procedure individually based on our methodology of what would be reasonable and medically necessary for the typical patient.

Comment: Several commenters disagreed with the CMS proposal to refine the clinical labor time for the ''Complete pre-procedure phone calls and prescription'' (CA005) activity from 10 minutes to 3 minutes for CPT code 95700. Commenters stated that instructions for video-EEG monitoring are lengthy and complicated, including the purpose of the test, patient preparation (hair care prior to test for electrode gel application, appropriate clothing), limitations on activities during the test, details of the location of testing, and type of equipment the patient will take home or be monitored with. Commenters stated that education typically takes 10 minutes.

Response: We disagree with the commenters that 10 minutes of clinical labor time would be typical for this activity. We note that the description of tasks provided by the commenters for the CA005 activity does not match the description of this activity code provided in the recommended materials for CPT code 95700, which instead listed calling the patient to confirm they have completed all pre-procedure activities, sanitizing and preparing any equipment that needs to be sanitized prior to each procedure, and collecting supplies to complete setup. The patient education tasks described by the commenters are contained in the CA011 activity code (''Provide education/obtain consent''), not the CA005 activity code. We continue to believe that many of the tasks described under the CA005 activity code are forms of indirect PE, and as we stated in the proposed rule, we believe that the RUC-recommended survey median clinical labor time of 10 minutes overstates the amount of direct clinical labor taking place. We continue to believe that it was more accurate to propose the survey 25th percentile clinical labor time of 3 minutes for this activity code to reflect the non-administrative tasks performed by the clinical staff.

Comment: Several commenters disagreed with the CMS proposal to refine the clinical labor time for the ''Provide education/obtain consent'' (CA011) activity from 13 minutes to 7 minutes. Commenters stated that the proposed 7 minutes was not ''more typical'' for this service, as long-term EEG monitoring is a service often performed on patients associated with neuropsychological impairment. Commenters stated that this condition means that the cognitive status of the patient may be challenged, making it more difficult to provide education, obtain consent, and review instructions. Commenters stated that people experiencing seizures who require a long-term EEG may be confused, sleepy, or forgetful, and making certain that patients are aware of the care instructions is important and can be a time-consuming endeavor. Commenters included a series of studies involving epilepsy research and requested that CMS finalize the RUC-recommended value of 13 minutes to reflect the patient mix undertaking these procedures.

Response: We appreciate the additional information provided by the commenters, including the studies included with their comments. We agree that there is a need for additional clinical labor time for patient education and consent in these procedures due to the patient population concerns identified by the commenters. This is the reason why we proposed 7 minutes for the CA011 activity code, which is more than triple the typical time of 2 minutes assigned to most other procedures for this task. We continue to believe that the proposed time of 7 minutes would be more typical for obtaining consent and reviewing patient education.

Comment: Several commenters disagreed with the CMS proposal of the RUC-recommended clinical labor time of 45 minutes for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity. Commenters stated that this time was undervalued and it was missing clinical labor time for applying the 10–20 system for electrode placement, following universal infection control policies, assessing skin breakdown risk at the electrode application site, using appropriate electrode application technique for at-risk patients, placing recording reference and ground electrodes in digital recording systems, and securing the headbox/transmitter system to protect against disconnection during patient movement. Commenters stated that the time that the EEG technologists takes to disconnect electrodes from the patient also appeared to be missing from the valuation of CPT code 95700 and needed to be included. The commenters stated that their EEG technologists averaged 128 minutes per patient for the activities covered in CPT code 95700, not the proposed 45 minutes.

Response: We disagree with the commenters that the tasks described in the CA016 activity code would typically require 128 minutes, almost triple the RUC-recommended time that we proposed. The same steps described by the commenter—such as preparing the patient, applying the electrodes, and testing the equipment—were part of the direct PE survey undertaken by the RUC, which returned a median time of 45 minutes and a 25th percentile time of 22 minutes. Although we agree with the commenter on the importance of these tasks, we do not believe that it would be typical for them to take 128 minutes given the survey data compiled by the RUC. We also note for the commenters that we did propose clinical labor time associated with disconnecting electrodes from the patient and taking down the monitoring equipment. This clinical labor time is listed under the CA024 clinical labor activity (''Clean room/equipment by clinical staff''), and we proposed the RUC-recommended 22 minutes for these tasks.

Comment: Several commenters disagreed with the CMS proposal of the RUC-recommended clinical labor time for the ''Perform procedure/service—NOT directly related to physician work time'' (CA021) activity across the TC Long Term EEG Monitoring family of codes. Commenters stated that the RUC survey data included more clinical labor time for the 2–12 hour EEG codes than for the longer duration 12–26 hour EEG codes, with a disproportionate amount of time given to the monitoring codes of shorter duration. Commenters provided several examples, such as CPT code 95706 having 57 minutes of clinical labor time as compared against CPT code 95709 having 50 minutes of clinical labor time. Commenters stated that the proposed clinical labor times were clearly in error and must be corrected in a final rule.

Response: We disagree with the commenters that the proposed clinical labor times were in error. The CA021 clinical labor times for the shorter 2–12 hour EEG codes have additional clinical labor time for maintenance activities, as

recommended by the RUC, which are not included for the longer 12–26 hour EEG codes due to the fact that these maintenance activities were stated not to be typically performed for the longer codes. We believe that many of these maintenance activities would not typically take place for the longer 12–26 hour EEG codes due to the fact that they will typically take place in the patient's home as opposed to the office setting. More importantly, we note that there are two technicians associated with each of the TC Long Term EEG Monitoring codes, one technician associated with monitoring tasks and another technician associated with non-monitoring tasks. We believe that looking at the clinical labor for only one of these two technicians presents an inaccurate picture of the coding structure. To use the same comparison between CPT codes 95706 and 95709 raised by the commenters, the second technician—the one present during the actual monitoring—has a clinical labor time of 40 minutes for the shorter 2–12 hour code (95706) and 120 minutes for the longer 12–26 hour code (95709), exactly as one would expect to see. We believe that it is highly misleading to look at only one of the two technicians in suggesting that the clinical labor times are in error and need correcting.

Comment: Several commenters stated that the proposed estimates for the non-monitoring clinical labor times associated with the continuous monitoring long term EEG codes were inaccurate. Commenters stated that the non-monitoring tasks involved in the provision of the services described in these codes are extensive, including: Reviewing patient clinical history, confirming the camera is displaying properly, reviewing patient events from prior monitoring, reviewing EEG recording for quality, checking electrode impedances for quality, documenting findings and notes, ensuring the patient is still in camera view, conducting maintenance during the patient session including contacting on-call maintenance support, repairing or replacing electrodes, counseling or instructing the patient if electrodes stop recording or a patient event occurs, communicating with the physician/QHP for events or triggers, reviewing and preparing data and video reports for the physician, analyzing and annotating the EEG test noting spike generator locations, and sending all data to the physician for reading. The commenters stated that the clinical labor time recommended by the RUC and proposed by CMS is substantially lower than what is required and fails to capture the time involved for all of the tasks outlined above.

Response: We disagree with the commenters that the proposed clinical labor time for these non-monitoring clinical labor activities would not be typical for these codes. We proposed the RUC-recommended clinical labor time for the service period of all four continuous monitoring EEG codes, which does include clinical labor time associated with the very same tasks listed by the commenter. For example, we proposed the RUC-recommended 72 minutes of clinical labor time for the CA021 (''Perform procedure/service—NOT directly related to physician work time'') activity for CPT code 95713, which included 10 minutes of clinical labor time for reviewing patient clinical history, current medications, and prior monitoring. Our proposal also included 34 minutes of clinical labor time for reviewing and preparing data, annotating the EEG, noting spike generator locations, documenting technologist initial notes, and sending all data to the practitioner for reading. We note that the very same clinical labor tasks described by the commenters were recommended by the RUC and proposed by CMS to include substantial (over 60 minutes) clinical labor time for these activities. We clarify for the commenters that the proposed clinical labor did include time for maintenance activities, with the non-monitoring technician repositioning or reattaching the electrodes as needed throughout the procedure time. In the absence of data from the commenters to support these significantly higher clinical labor times, we continue to believe that our proposed times are the most accurate values.

Comment: Several commenters disagreed with the CMS proposal to refine the clinical labor time for the ''Coordinate post-procedure services'' (CA038) activity from either 11 minutes to 5 minutes or from 22 minutes to 10 minutes as appropriate for the CPT code in question. Commenters stated that CMS used a comparison to the clinical labor time for CPT code 95812 in making this refinement, however CPT code 95812 describes a 41–60 minute study as opposed to long term EEG monitoring. Commenters stated that selecting the relevant EEG data to be archived and then archiving it would take considerably longer due to the longer duration of the reviewed codes. Commenters urged CMS to finalize the RUC-recommended clinical labor times instead of the proposed values.

Response: We appreciate the additional information provided by the commenters regarding the shorter duration of CPT code 95812. Based on the feedback from the commenters, we would not finalize our proposed refinements and would instead finalize the RUC-recommended clinical labor time for the ''Coordinate post-procedure services'' (CA038) activity at either 11 minutes or 22 minutes as appropriate for the CPT code in question if we were to adopt national pricing. We would also finalize the equipment time for the Technologist PACS workstation (ED050) to match the clinical labor time for the CA038 activity if we were to adopt active pricing.

Comment: A commenter disagreed with both the RUC-recommended and CMS-proposed clinical labor times for CPT code 95700. The commenter stated that this code does not specify whether the service is being performed in a physician's office or the patient's home, and this lack of differentiation makes it difficult to provide an accurate picture of the service. The commenter stated that the proposed clinical staff time for CPT code 95700 of 96 minutes was approximately half of the time actually required to do a set up in the patient's home and does not include any time for the take down. The commenter stated that in the home setting the procedure set up is typically 3 hours and take down is one hour. The commenter also stated that the proposed clinical labor for CPT code 95700 did not include any travel time, which is usually between 1 and 3 hours in each direction. The commenter stated that additional clinical labor time should be added to reflect this setup and takedown time along with 3 hours of clinical labor time to reflect travel.

Response: We disagree with the commenter that several additional hours of clinical labor time should be added to CPT code 95700. Although we do not believe that the RUC is the exclusive source of information used in valuation of PFS services, in the absence of alternative data used to value new services, we believe that the direct PE recommendations from the RUC are the key source to use for valuation. We believe that the direct PE survey used by the RUC for CPT code 95700 represents the best information available for this service, and given that we did not receive data from the commenter to support alternate valuations, we believe that the clinical labor times that we proposed, based on either the median or 25th percentile values from the RUC's direct PE survey, represent the most accurate times. We also note for the commenter that we did propose clinical labor time associated with disconnecting electrodes from the patient and taking down the monitoring

equipment. This clinical labor time is listed under the CA024 clinical labor activity (''Clean room/equipment by clinical staff''), and we proposed the RUC-recommended 22 minutes for these tasks.

With regard to the driving times mentioned by the commenter, we did not propose clinical labor time for these activities because we consider them to be a type of office expense, and therefore, a form of indirect PE. Transportation costs are not individually allocable to a particular patient for a particular service, and therefore, constitute indirect PE under our methodology.

Comment: A commenter disagreed with both the RUC-recommended and proposed clinical labor times for CPT codes 95715 and 95716. The commenter stated that the clinical labor inputs failed to include time for tasks such as maintenance and pruning, and the proposed clinical labor assumed that the maximum number of patients are being monitored at all times. The commenter stated that the clinical labor inputs also do not include time for data pruning, a critical component of EEG monitoring that allows the neurologist to more efficiently read the test results. The commenter stated that approximately 4 hours of clinical labor time should be added to these codes to reflect these missing inputs.

Response: We disagree with the commenter that this additional clinical labor time would be typical for CPT codes 95715 and 95716. We proposed the RUC-recommended clinical labor time for the service period of both codes, which does include clinical labor time associated with data management. For example, we proposed the RUC-recommended 70 minutes of clinical labor time for the CA021 (''Perform procedure/service—NOT directly related to physician work time'') activity for CPT code 95715, which included 60 minutes of clinical labor time for reviewing and preparing data, annotating the EEG, noting spike generator locations, documenting technologist initial notes, and sending all data to the practitioner for reading. The recommended materials stated that this data preparation would typically take place during the patient session, as opposed to separate from it, and we have no reason to belief that this would not be the case.

Comment: Several commenters stated that it was inappropriate for CMS to assume that IDTFs typically operate at maximum efficiency, providing continuous monitoring to 4 patients at the same time and intermittent monitoring to 12 patients at the same time. Commenters stated that the RUC survey that was the basis for the proposed duration-of-monitoring assumptions indicated that it is more typical for continuous monitoring to be provided to three patients at the same time. Commenters stated that they anticipated that the time associated with monitoring would increase under the new CPT nomenclature, since the new nomenclature provides an incentive for increased physician involvement in the monitoring process, which likely would increase physician-technologist communication and coordination. Commenters also stated that some facilities will not have enough EEG machines to monitor 12 patients at a time under intermittent monitoring.

Response: We continue to believe that 4 patients would typically be monitored at a time under continuous monitoring and that 12 patients would typically be monitored at a time during intermittent monitoring. While it is true that the RUC survey initially suggested that 3 patients would be monitored at a time during continuous monitoring, the RUC updated its clinical labor times to reflect an assumption of 4 patients being monitored simultaneously based on a consensus opinion that this more accurately reflected the typical practice pattern. With regard to the specific issue raised by the commenters, we agree that some facilities may not have enough EEG machines to monitor 12 patients at a time, but, conversely, some facilities may be able to monitor more than 12 patients at a time. Our methodology is based on the typical case and is not intended to cover every possible situation that may occur across all providers. The typical case for long term EEG monitoring was recommended to us and we believe to be 4 patients at a time for continuous monitoring and 12 patients at a time for intermittent monitoring.

Comment: Several commenters disagreed with both the RUC-recommended and proposed supplies for CPT code 95700. Commenters stated that there were many additional supplies that should also be included in this code, such as 28 disposable electrodes, 9-volt lithium batteries, a battery tester, foam electrodes, a HIPAA-compliant lockbox, utility scissors, disinfecting Cavi-wipes, protective skin barrier wipes, disposable sterile sheet pads, Purell hand sanitizer, cotton-tip applicators, disposable Hefty bags, and patient safety labels. Commenters provided invoices for some of these supplies and requested that CMS add them to the direct PE inputs for CPT code 95700.

Response: We disagree with the commenters that these additional supplies should be added to the direct PE inputs for CPT code 95700. Aside from proposing to refine the quantity of the non-sterile gloves (SB022) supply from 3 to 2, due to the fact that we believed the third pair of gloves to be duplicative, we proposed the RUC-recommended supplies for this code. We believe that these recommended supplies, based on the direct PE survey for CPT code 95700, represent the most accurate data associated with this procedure. We continue to believe that the use of disposable electrodes would not be typical for CPT code 95700, as the recommended materials specifically stated that reusable electrodes would instead be typical. Many of the other supplies listed by the commenters were never included as supplies in the predecessor EEG monitoring codes, or they represent office expenses that we would consider to be indirect PE, such as the lockbox used for storage or the trash bags used for disposal. We continue to believe that the direct PE survey used by the RUC for CPT code 95700 represents the best supply information available for this service.

Comment: Several commenters disagreed with the CMS proposal to refine the equipment time for the Technologist PACS workstation (ED050) to match the clinical labor time proposed for the CA038 activity. Commenters stated that the work performed on the PACS station for long term EEG monitoring was different than other PACs stations, as the PAC station is where the EEG recording data and video data is processed, clipped, and ultimately saved. Commenters stated that given the duration of long term EEG recordings, the RUC-recommended equipment times for the technologist PACS workstation are more accurate and representative of the work performed.

Response: We disagree with the commenters that the technologist PACS workstation (ED050) equipment time is used differently for long term EEG monitoring procedures as compared to the use of the same workstation in other services. The fact that EEG recording data is processed and clipped on the technologist PACS workstation does not provide a rationale for additional equipment time, as similar activities take place in other services as well. We do not understand why the workstation would be in use for double the amount of clinical labor assigned to the CA038 (''Coordinate post-procedure services'') activity code, as the RUC recommended, and we continue to believe that the equipment time should, generally

speaking, match the clinical labor time in which the equipment item is in use.

Comment: Several commenters disagreed with the CMS proposal to refine the equipment time for the ambulatory EEG review station (EQ016) equipment for the four continuous monitoring procedures, CPT codes 95707, 95710, 95713, and 95716. Commenters stated that it was not typical for a review station to be hooked up to four monitors, as CMS stated in the proposed rule, and instead 2–3 monitors would be typical. Commenters stated that it would be more appropriate to assign EQ016 minutes by multiplying CA021 clinical labor time 2 or 3 times plus prep time, rather than the refined times proposed by CMS.

Response: We appreciate the additional information provided by the commenter stating that it would be typical for a review station to be hooked up to 2–3 monitors at a time. Based on the information from the commenters, we are refining the equipment times for the ambulatory EEG review station (EQ016) equipment to reflect the belief that having a review station connected to 3 monitors at a time is the typical case. This results in the equipment times increasing slightly for all four CPT codes, such as CPT code 95707 increasing from the proposed 150 minutes to a new time of 190 minutes. Therefore, we would finalize EQ016 equipment times of 190 minutes for CPT code 95707, 520 minutes for CPT code 95710, 194 minutes for CPT code 95713, and 535 minutes for CPT code 95716 if we were to adopt active pricing for these codes.

Comment: Several commenters disagreed with the CMS proposal to refine the equipment time for the ambulatory EEG review station (EQ016) equipment in the PC codes (CPT codes 95717–95726) based on the belief that the use of the ambulatory EEG review station is analogous in these procedures to the use of the professional PACS workstation (ED053) in other procedures. Commenters stated that the EEG review station is used during the postservice work period and should be included in the PE inputs for all of the PC codes. Commenters stated that often the referring physician calls the physician providing the service to ask questions about the recording, and the providing physician will pull up the record on an EEG review station and go over the questions and provide responses with the inquiring physician. Commenters stated that this is similar to when a physician asks a radiologist about an MRI or CT report, as the radiologist opens the radiology review station to view the images while discussing with the referring physician the questions and answers.

Response: We continue to disagree with the commenters about assigning the full work time to the ambulatory EEG review station (EQ016) equipment in the PC codes. We appreciate the analogy provided by the commenters to the use of a review station for an MRI or CT report; as we wrote in the proposed rule, we believe that the use of the ambulatory EEG review station is analogous in these procedures to the use of the professional PACS workstation (ED053) in other procedures, and we do not assign equipment time for the professional PACS workstation in MRI or CT procedures based on review by the practitioner in the postservice work period. We continue to believe that it better serves the purpose of relativity to propose an equipment time for the ambulatory EEG review station equal to half the preservice work time (rounded up) plus the intraservice work time for CPT codes 95717 through 95726. We also continue to note that the work descriptors for CPT codes 95717–95726 make no mention of the ambulatory EEG review station in the postservice work period. Perhaps this equipment is used ''often'' as the commenters stated but that does not necessarily mean that its use is typical for the procedures.

Comment: A commenter disagreed with the proposed price of $26,410.95 for the equipment, ''EEG, digital, prolonged testing system with remote video, for patients home use'' (EQ394). The commenter submitted two invoices indicating slightly higher pricing for this equipment item and requested that CMS incorporate them into the equipment price.

Response: We appreciate the submission of additional invoices from the commenter. Based on this information, we are finalizing an increase in the price of ''EEG, digital, prolonged testing system with remote video, for patients home use'' (EQ394) equipment from the proposed $26,410.95 to $29,496.98 based on the submission of three total invoices.

Comment: A commenter disagreed with the proposed equipment items for CPT codes 95715 and 95716. The commenter stated that these codes assume use of an EEG review station, ambulatory (EQ016) equipment item at a price of $7,950 but the actual equipment used is more sophisticated and is better described as an EEG monitoring system (EQ019) equipment item at a price of $33,389.29.

Response: We disagree with the commenter that the EEG monitoring system (EQ019) equipment would be more typical for these procedures than the proposed EEG review station, ambulatory (EQ016) equipment. The EQ019 equipment is a specialized item utilized by only two CPT codes, 91132 and 91133, which are both transcutaneous diagnostic Electrogastrography procedures. By contrast, the EQ016 equipment is currently utilized in CPT code 95950, an actual EEG code that serves as a direct predecessor for many of the new long term EEG monitoring codes. We agree with the RUC that the use of the EQ016 equipment would be typical for these procedures.

Comment: A commenter stated that the bedroom furniture (EF003) equipment was included only in CPT codes 95706, 95707, 95712, and 95713, the EEG codes for 2–12 hours monitoring duration. The commenter stated that the need for furniture does not discontinue if the patient requires longer term monitoring, and requested that CMS add the EF003 equipment to CPT codes 95709, 95710, 95715, and 95716.

Response: As we noted elsewhere in the comment responses, the 2–12 hour EEG monitoring codes were reviewed by the RUC and recommended to CMS with the understanding that they were typically performed in the office setting, whereas the 12–26 hour EEG monitoring codes were reviewed by the RUC and then recommended to CMS with the understanding that they were typically performed in the home setting. Although we agree with the commenter that the patient would typically be resting on some kind of furniture in the longer EEG monitoring codes, there is no equipment cost in these codes because the furniture would be located in the patient's own home and not in the office setting.

Comment: Several commenters disagreed with both the RUC-recommended and CMS-proposed equipment items. These commenters stated that the proposed equipment reflects three different systems for EEG/vEEG recording, ranging in cost from $7,950 to $46,750, even though the same type of system is used for all of the monitoring described in the new EEG TC codes. Commenters stated that the proposed inputs reflected no additional equipment cost for video equipment and had an unrealistically long useful life. Commenters stated that the proposed inputs failed to recognize the software that is necessary to facilitate physician monitoring of testing in real time, as anticipated by new CPT codes 95717–95720.

Response: We disagree with the commenters regarding these equipment issues. We proposed the use of different

equipment items to reflect the fact that the monitoring for the TC codes is captured by different types of equipment depending on the type of monitoring and the site of service. For example, the ''EEG, digital, prolonged testing system with remote video, for patients home use'' (EQ394) equipment is designed to be used to capture video recordings that take place in the patient's home. In contrast, the ''EEG monitor, digital, portable'' (EQ014) equipment does not contain a video component, and we proposed to include it only in the non-video codes in this family. Under our resource-based methodology, it would not be accurate to assign the same equipment to each TC code in the family given that they describe different services with differing equipment needs. Similarly, we disagree with the statement from the commenters that the proposed inputs reflected no additional equipment cost for video equipment. As we noted, we proposed different and more expensive equipment types for the codes in the family that use video equipment as opposed to those that do not.

We also disagree with the commenters that we proposed unrealistically long useful life durations for the equipment. The only new equipment item used in this family of codes is the EQ394 equipment, for which we proposed a useful life of 7 years. This matches the same useful life of 7 years which has long been established for the EQ014, EQ015, and EQ017 equipment items, all of which involve EEG monitoring and all of which are utilized by codes in this family. We believe that the new EQ394 equipment would share this same useful life assumption with the other previously existing types of EEG monitoring equipment. We also disagree with the commenters that the direct PE inputs lack the necessary software to facilitate physician monitoring of testing in real time. The equipment items utilized for video monitoring, EQ017 and EQ394, both include basic software in their purchase prices, which helps to explain why they are priced at a higher rate than the non-video EQ014 monitoring equipment.

Comment: Several commenters suggested that the proposed equipment times were understated. Commenters stated that the monitoring system equipment times appeared to reflect only 8 hours of actual monitoring time (480 minutes) for the 2–12 hour codes and 24 hours (1,440 minutes) for the 12–26 hour codes. The commenter stated that the proposed equipment times only reflected the time for their direct use to monitor patients, and failed to reflect the time necessary for the delivery and return of equipment, set up, disconnect, or cleaning of equipment.

Response: We disagree with the commenter that the proposed equipment times were understated. We note that the ''EEG monitor, digital, portable'' (EQ014) equipment did include proposed equipment time associated with patient setup and disconnecting of equipment in CPT code 95700. The other equipment items did not require this kind of set up, disconnecting, and cleaning time (such as the Technologist PACS workstation and ambulatory EEG review station). We also note for the commenters that time allocated for delivery and return of equipment is an office expense that we consider to be a form of indirect PE under our methodology.

Comment: Several commenters stated that the review station requires use of equipment that is not otherwise recognized in the proposed rule, including a high spec laptop PC, wide screen monitors, advanced review software, high bandwidth internet connectivity, software for security purposes, and data storage that is HIPAA compliant. Commenters stated that CMS failed to recognize substantial IT, software and server costs, including uploading and storing for large patient data files. One commenter included an invoice for a storage area network (SAN) displaying a paid purchase price of $15,992.40 while another commenter submitted an invoice for a portable external hard drive at a price of $51.89.

Response: These types of equipment listed by the commenters are administrative expenses that we are considered forms of indirect PE under our methodology. Although we agree that providers will have a need for laptops, monitors, internet connectivity, data storage, and software security systems, these expenses are not unique to individual procedures and constitute forms of general office expenses. We note as an example that we do not assign separate direct PE for higher electricity costs to diagnostic imaging procedures as compared to cognitive evaluation procedures; these expenses are part of the office costs of running a practice, not specific to individual procedures. We continue to believe that these costs are appropriately captured via the indirect PE methodology as opposed to being included as a separate direct PE input.

Comment: A commenter stated that there appeared to be a discrepancy in the RUC survey results sent to CMS. The commenter stated that, under clinical labor codes (CA021) for patient/family education and for internal communication, time was provided for each code, however there was no time allotted for these clinical labor activities. The commenter stated that these activities are necessary for the conduct of long-term EEG services and asked CMS to clarify which data point was used within the proposed rule.

Response: We remind the commenter that CMS does not publish the RUC recommendations, and we cannot speak as to whether or not they may contain errors. We review and make our own assessment of the RUC recommendations. We remind readers that the direct PE inputs for CY 2020 are displayed in the CY 2020 direct PE input files, available on the CMS website under the downloads for the CY 2020 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs for all of the codes in the Long Term EEG Monitoring family. We are finalizing the direct PE inputs as proposed for the PC-only codes in the family (CPT codes 95717–95726) and finalizing the assignment of contractor pricing for the TC-only codes in the family (CPT codes 95700–95716). As we have summarized above, commenters have raised some significant concerns regarding the usefulness of these codes in establishing appropriate values for these services. Also as we have noted in the preceding discussion, we continually seek updated information, including and especially empirical data, regarding the resources involved in furnishing PFS services.

In the context of the concerns raised regarding the applicability of the new code set in various settings of care and by the services furnished to patients with varying needs, we are persuaded by commenters that we should maintain the stability inherent in contractor pricing despite consideration of RUC-recommended direct PE inputs for these TC services. While many of the same concerns apply to the PC component of these services, we note that the professional component of these services are currently valued using recommendations originally furnished by the RUC. Consequently, we believe it is appropriate to maintain national payment rates for the professional component of these services. However, we continue to seek information regarding these services and how the changes in valuation and coding might affect appropriate access to care for beneficiaries. For example, we would consider establishing G-codes specific for services in particular settings of care

in future rulemaking should such access concerns become apparent.

(64) Health and Behavioral Assessment and Intervention (CPT Codes 96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, and 96171)

The 2001 Health and Behavior Assessment and Intervention (HBAI) RUC valuations were based on the old CPT code 90801 (*Psychiatric diagnostic interview evaluation*), a 60-minute service. The RUC originally recommended the Health and Behavior Assessment and Intervention procedures to be 15-minute services, approximately equal to one-quarter of the value of CPT code 90801, which we finalized without refinements. While the RUC may have assumed that these services would typically be reported in four, 15-minute services per single patient encounter, in actual claims data, there is wide variation in the number of services provided and submitted. The RUC reconsidered their rationale for the original RUC-recommended valuation of this family of codes in September 2018. The CPT Editorial Panel deleted the six existing Health and Behavior Assessment and Intervention procedure CPT codes and replaced them with nine new CPT codes.

The six deleted CPT codes include CPT code 96150 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment*), CPT code 96151 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; re-assessment*), CPT code 96152 (*Health and behavior intervention, each 15 minutes, face-to-face; individual*), CPT code 96153 (*Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)*), CPT code 96154 (*Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)*), and CPT code 96155 (*Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)*).

The nine replacement HBAI CPT codes include CPT code 96156 (*Health behavior assessment, including re-assessment (i.e., health-focused clinical interview, behavioral observations, clinical decision making)*), CPT code 96158 (*Health behavior intervention, individual, face-to-face; initial 30 minutes*), CPT code 96159 (*Health behavior intervention, individual, face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*), CPT code 96164 (*Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes*), CPT code 96165 (*Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*), CPT code 96167 (*Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes*), CPT code 96168 (*Health behavior intervention, family (with the patient present), face-to-face each additional 15 minutes (list separately in addition to code for primary service)*), CPT code 96170 (*Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes*), CPT code 96171 (*Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (list separately in addition to code for primary service*).

We proposed the RUC-recommended work RVUs for each of the codes in this family as follows.

- For CPT code 96156, we proposed a work RVU of 2.10.
- For CPT code 96158, we proposed a work RVU of 1.45.
- For CPT code 96159, we proposed a work RVU of 0.50.
- For CPT code 96164, we proposed a work RVU of 0.21.
- For CPT code 96165, we proposed a work RVU of 0.10.
- For CPT code 96167, we proposed a work RVU of 1.55.
- For CPT code 96168, we proposed a work RVU of 0.55.
- For CPT code 96170, we proposed a work RVU of 1.50 (but this code will be non-covered by Medicare).
- For CPT code 96171, we proposed a work RVU of 0.54 (but this code will be non-covered by Medicare).

We proposed the RUC-recommended direct PE inputs for all of the CPT codes in this family without refinement.

We received public comments on the proposed valuation of the codes in the Health and Behavioral Assessment and Intervention family. The following is a summary of the comments we received and our responses.

Comment: The total number of comments for the HBAI CPT codes are from Psychologist who are uniformly pleased to see that CMS has accepted all of the AMA RUC's recommended increases for the Health Behavior Assessment and Intervention (HBAI) services and that the American Psychological Association further urges CMS to make payable CPT code 96170 and 96171, both Family Intervention services without the patient being present.

Response: As with the original HBAI non-covered codes, where the patient is not present during the service, that will remain true with the new replacement CPT code 96170 and 96171 where they will retain their non-covered status.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Health and Behavioral Assessment and Intervention code family as proposed.

(65) Cognitive Function Intervention (CPT Codes 97129 and 97130)

In 2017, we received HCPAC recommendations for new CPT code 97127 (*Development of cognitive skills to improve attention, memory, problem solving, direct patient contact, 1*) that described the services under CPT code 97532 (*Development of cognitive skills to improve attention, memory, problem solving, direct patient contact, each 15 minutes*). CPT code 97532 was scheduled to be deleted and replaced by the new untimed code CPT code 97127. In the CY 2018 PFS final rule (82 FR 53074 through 53076), however, we suggested that CPT code 97127 as an untimed/per day code did not appropriately account for the variable amounts of time spent with a patient depending upon the discipline and/or setting and thus assigned the code a procedure status of ''I'' (Invalid). In place of CPT code 97127, we established a new HCPCS G code, G0515 (*Development of cognitive skills to improve attention, memory, problem solving, direct patient contact, each 15 minutes*), with a work RVU of 0.44. HCPCS code G0515 maintained the descriptor and values from the former CPT code 97532.

In September 2018, the CPT Editorial Panel revised CPT code 97129 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing and sequencing tasks), direct (one-to-one) patient contact; initial 15 minutes*) and created an add-on code, CPT code 97130 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing and*

sequencing tasks), direct (one-to-one) patient contact; each additional 15 minutes (list separately in addition to code for primary procedure)).

We proposed the RUC-recommended work RVUs of 0.50 for CPT code 97129 and 0.48 for CPT code 97130. We also proposed the RUC-recommended direct PE inputs for all codes in the family. Additionally, we proposed to designate CPT codes 97129 and 97130 as sometime therapy codes because the services might be appropriately furnished by therapists under the outpatient therapy services benefit (includes physical therapy, occupational therapy, or speech-language pathology) or outside the therapy benefit by physicians, NPPs, and psychologists.

We received public comments on the proposed valuation of CPT codes 97129 and 97130. The following is a summary of the comments we received and our response.

Comment: Commenters uniformly requested that we adopt the new cognitive function intervention codes at the values we proposed.

Response: We appreciate the support for our proposals from the commenters.

Comment: A commenter stated that CMS did not indicate whether HCPCS code G0515 (*Cognitive skills development, each 15 minutes*) will be deleted. The commenter requested that CMS delete HCPCS code G0515 given the proposal of new CPT codes describing the treatment of cognitive impairments.

Response: We proposed to delete HCPCS code G0515 and replace it with new CPT codes 97129 and 97130, as detailed in our CY 2019 Analytic Crosswalk to CY 2020 public use file issued along with the proposed rule. We can confirm for the commenter that HCPCS code G0515 will be deleted for CY 2020.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Cognitive Function Intervention family as proposed. We are also finalizing our proposal to designate both codes as sometime therapy codes.

(66) Open Wound Debridement (CPT Codes 97597 and 97598)

CPT code 97598 (*Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof*) was identified by the RUC on a list of services that were originally surveyed by one specialty but are now typically performed by a different specialty. It was reviewed along CPT code 97597 (*Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less*) at the October 2018 RUC meeting.

We disagree with the RUC-recommended work RVU of 0.88 for CPT code 97597 and we proposed a work RVU of 0.77 based on a crosswalk to CPT code 27369 (*Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography*). CPT code 27369 is a recently-reviewed code with the same intraservice time of 15 minutes and a total time of 28 minutes, 1 minute fewer than CPT code 97597. In reviewing this code, we noted that the recommended intraservice time is increasing from 14 minutes to 15 minutes (7 percent), and the recommended total time is increasing from 24 minutes to 29 minutes (21 percent); however, the RUC-recommended work RVU is increasing from 0.51 to 0.88, which is an increase of 73 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, modest increases in time should be appropriately reflected with a commensurate increase the work RVUs. In the case of CPT code 97597, we believed that it is more accurate to propose a work RVU of 0.77 based on a crosswalk to CPT code 27369 to account for these modest increases in the surveyed work time. We also note that even at the proposed work RVU of 0.77 the intensity of this procedure as measured by IWPUT is increasing by more than 50 percent over the current value.

We proposed the RUC-recommended work RVU of 0.50 for CPT code 97598. We are also proposing the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Open Wound Debridement family. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the CMS proposed work RVU of 0.77 for CPT code 97597 and stated that CMS should instead finalize the RUC-recommended work RVU of 0.88. Commenters stated that the work RVU of 0.77 for the proposed CMS crosswalk code, CPT code 27369, was derived by CMS using a reverse building block methodology from the RUC-recommended work RVU of 0.96. Commenters stated that the use of the reverse building block methodology to develop a work RVU for CPT code 27369 was faulty, and therefore, this code was not an appropriate choice to serve as a crosswalk for CPT code 97597.

Response: We disagree with the commenters that CPT code 27369 was an inappropriate choice to serve as a crosswalk. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including the use of building block methodologies (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code, and building block methodologies have long been used in developing work RVUs under the PFS. More importantly, the work valuation of CPT code 27369 was finalized at 0.77 in the CY 2019 PFS final rule (83 FR 59525) and additional discussion of this code's work RVU is out of scope for this rule. We continue to believe that it is more accurate to propose a work RVU of 0.77 for CPT code 97597 based on a crosswalk to CPT code 27369 to account for the modest increases in the procedure's surveyed work time.

Comment: Several commenters stated that due to flawed methodologies in the survey process, CPT code 97597 was incorrectly valued in 2010, and therefore, it was invalid for CMS to compare the current time and work to the surveyed time and work of the newly created codes in the family. Commenters also stated that since CPT code 97597 was last valued there has been a change in the patient population, and therefore, the RUC-recommended increase in work time and work RVU was not commensurate with the flawed current work times and work RVU.

Response: We believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: A commenter disagreed with the proposed valuation of CPT code 97597 based on a comparison to CPT codes 99212 and 99213, stating that the methodology employed for this code family was contradictory to how the Agency reviewed other codes in this same proposed rule for similar services. The commenter stated that CMS proposed a work RVU of 0.75 for CPT code 99212 compared with a proposed work RVU of 0.77 for CPT code 97597, a difference of only 3 percent, even though the total time for CPT code 97597 is 61 percent greater. The commenter stated that a similar comparison could also be made using CPT code 99213 (proposed work RVU = 1.30, total time = 30 minutes) which requires a low level of medical decision-making similar to CPT code 97597. The commenter stated that when considering work per unit time, the proposed work RVU for CPT code 97597 significantly undervalues the physician work compared to CPT codes 99212 and 99213.

Response: We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work. We clarify again that we do not treat all components of physician time as having identical intensity. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. For more details on our methodology for developing work RVUs, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277). For the specific case of CPT code 97597, we note again that the proposed work RVU was not based on a time ratio or a building block methodology, but instead based on a crosswalk to CPT code 27369. This was only one of several different codes that we could have chosen for a crosswalk; we also considered CPT code 36470 (*Injection of sclerosant; single incompetent vein (other than telangiectasia)*) and CPT code 43756 (*Duodenal intubation and aspiration, diagnostic, includes image guidance; single specimen (e.g., bile study for crystals or afferent loop culture)*), both of which have similar time values and work RVUs of 0.75 and 0.77 respectively. We disagree with the commenters that CPT codes 99212 and 99213 are appropriate choices for comparisons, as they do not share the same 0 day global period as CPT code 97597.

Comment: Several commenters stated that they supported the proposal of the RUC-recommended work RVU for CPT code 97598 and the RUC-recommended direct PE inputs for both codes.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Open Wound Debridement family as proposed.

(67) Negative Pressure Wound Therapy (CPT Codes 97607 and 97608)

In the CY 2013 final rule with comment period, we created two HCPCS codes to provide a payment mechanism for negative pressure wound therapy services furnished to beneficiaries using equipment that is not paid for as durable medical equipment: G0456 (*Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters*) and G0457 (*Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 sq. cm*). For CY 2015, the CPT Editorial Panel created CPT codes 97607 (*Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate*) and 97608 (*Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate*) to describe negative pressure wound therapy with the use of a disposable system. In addition, CPT codes 97605 (*Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters*) and 97606 (*Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters*) were revised to specify the use of durable medical equipment. Based upon the revised coding scheme for negative pressure wound therapy, we deleted the G-codes. Due to concerns that we had with these services, we contractor priced CPT codes 97607 and 97608 beginning in CY 2015 (79 FR 67670). In the CY 2016 PFS final rule (80 FR 71005), in response to comment expressing disappointment with CMS' decision to contractor price these codes, we noted that there were obstacles to developing accurate payment rates for these services within the PE RVU methodology, including the indirect PE allocation for the typical practitioners who furnish these services and the diversity of the products used in furnishing these services.

We have received repeated requests from stakeholders, including in comments received in response to the CY 2019 PFS final rule, to assign an active status to these codes, meaning we would assign rates to the codes rather than allowing them to be contractor priced. In that rule, (83 FR 59473), we noted that we received a request that CMS should assign direct cost inputs and PE RVUs to CPT codes 97607 and 97608, and we indicated that we would

take this feedback from commenters under consideration for future rulemaking.

In response to stakeholder feedback, we evaluated the codes and determined there was adequate volume to assign an active status. We proposed to assign an active status to CPT codes 97607 and 97608 and we proposed the work RVUs as recommended by the RUC that we received for CY 2015 when the CPT Editorial Panel created these codes. Thus, we proposed a work RVU of 0.41 for CPT code 97607 and a work RVU of 0.46 for CPT code 97608. Similarly, we proposed the RUC-recommended direct PE inputs originally for CY 2015 with the following refinement: For the clinical labor activity ''check dressings & wound/home care instructions/ coordinate office visits/prescriptions,'' we are refining the clinical labor time to the standard 2 minutes for this task. In addition, the direct inputs for these codes include the new supply item, ''kit, negative pressure wound therapy, disposable'' (SA131). A search of publicly available commercial pricing data indicates that a unit price of approximately $100 is appropriate, and therefore, we proposed this price for this supply item. In the proposed rule, we sought invoices to more accurately price this kit.

We received public comments on the proposed valuation of the codes in the Negative Pressure Wound Therapy family. The following is a summary of the comments we received and our responses.

Comment: A commenter expressed support for our proposed work and direct PE values and appreciated CMS changing the payment status to active. Another commenter stated that they did not object to the proposed direct PE refinements and stated that these refinements matched the changes in time as compared with CPT codes 97605 and 97608.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters supported the proposal to establish a national fee schedule amount for application of single-use disposable negative pressure wound therapy billed with CPT codes 97607 and 97608. However, the commenters disagreed with the proposed price of $100 for the disposable negative pressure wound therapy kit (SA131) supply. One commenter stated that although single-use disposable negative pressure wound therapy device costs can vary, the average price paid by office-based physicians is $273.55 for these PICO single-use negative pressure wound therapy devices. The commenter submitted five invoices to support this price for the SA131 supply, and requested that CMS update the proposed price. Another commenter agreed that the proposed price does not reflect the actual invoiced prices by manufacturers or suppliers/distributors on the market today, and submitted additional paid invoices showing the average supply cost for the disposable negative pressure wound therapy kit being between $208 and $494 depending on the type of disposable negative pressure wound therapy deployed.

Response: We appreciate the submission of additional invoices on the part of the commenter. However, when we reviewed the pricing for the SA131 supply, we continued to find disposal negative pressure wound therapy kits available for purchase online for roughly $100. We compared the kits on the submitted invoices to the kits available for purchase online, and as far as we can determine, they appear to describe the same product, with both kits containing a dressing of the same size and a disposable pump. In light of the additional pricing information supplied by the commenters, we are finalizing an increase in the price of the disposable negative pressure wound therapy kit (SA131) supply, but only to the lower end of the invoice prices submitted by the commenters. We are finalizing a price of $208 for the SA131 supply based on the lower end of the average supply cost provided by the commenters, as there appear to be kits that are readily available at both higher and lower prices. We believe that the $208 price point will serve as a proxy for the typical purchase price of these kits.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Negative Pressure Wound Therapy family as proposed.

(68) Ultrasonic Wound Assessment (CPT Code 97610)

In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the Committee. CPT code 97610 (*Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*) was flagged for CPT 2015 and reviewed at the October 2018 RAW meeting. The Workgroup indicated that the utilization is continuing to increase for this service, and recommended that it be resurveyed for physician work and PE for the January 2019 RUC meeting.

We proposed the RUC-recommend work RVU of 0.40 for CPT code 97610. We also proposed the RUC-recommended direct PE inputs for CPT code 97610.

We received public comments on the proposed valuation of the codes in the Ultrasonic Wound Assessment family. The following is a summary of the comments we received and our responses.

Comment: A commenter supported our proposal for this code.

Response: We appreciate the support from the commenter.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU and direct PE inputs as proposed.

(69) Online Digital Evaluation Service (E-Visit) (CPT Codes 98970, 98971, and 98972)

In September 2018, the CPT Editorial Panel deleted two codes and replaced them with six new non-face-to-face codes to describe patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office. The HCPAC reviewed and made recommendations for CPT code 98970 (*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*), CPT code 98971 (*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*), and CPT code 98972 (*Qualified nonphysician qualified healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*). CPT codes 99421–99423 are for practitioners who can independently bill E/M services while CPT codes 98970–98972 are for practitioners who cannot independently bill E/M services.

The statutory requirements that govern the Medicare benefit are specific regarding which practitioners may bill for E/M services. As such, when codes are established that describe E/M services that fall outside the Medicare benefit category of the practitioners who may bill for that service, we have typically created parallel HCPCS G-codes with descriptors that refer to the performance of an ''assessment'' rather than an ''evaluation''. We acknowledge

that there are qualified non-physician health care professionals who will likely perform these services. Therefore, for CY 2020, we proposed separate payment for online digital assessments via three HCPCS G-codes that mirror the RUC recommendations for CPT codes 98970–98972. The proposed HCPCS G codes and descriptors are as follows:

- HCPCS code G2061 (*Qualified nonphysician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*);
- HCPCS code G2062 (*Qualified nonphysician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*); and
- HCPCS code G2063 (*Qualified nonphysician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*).

For CY 2020, we proposed a work RVU of 0.25 for CPT code G2061, which reflects the RUC-recommended work RVU for CPT code 98970. For HCPCS codes G2062 and G2063, we believe that the 25th percentile work RVU associated with CPT codes 98971 and 98972 respectively, better reflects the intensity of performing these services, as well as the methodology used to value the other codes in the family, all of which use the 25th percentile work RVU. Therefore, we proposed a work RVU of 0.44 for HCPCS code G2062 and a work RVU of 0.69 for HCPCS code G2063.

We proposed the direct PE inputs associated with CPT codes 98970, 98971, and 98972 for G2061, G2062, and G2063 respectively.

We received public comments on the proposed valuation of the codes in the Online Digital Evaluation Service (e-Visit) family. The following is a summary of the comments we received and our responses.

Comment: Many commenters were supportive of separate payment for these services, although a number expressed reservations with the use of HCPCS G-codes and encouraged CMS to work with the CPT editorial panel to make refinements to the CPT code descriptors. Some commenters stated that the proposed values for HCPCS codes GPPP2 and GPPP3 undervalued the work associated with these services and encouraged CMS to adopt the RUC recommended work RVUs of 0.50 and 0.80, respectively. Commenters stated that these codes were valued to be identical to the work RVUs associated with the corresponding physician codes, 99422 and 99423.

Commenters from specialty societies representing audiologist and speech language pathologists, who are ineligible to bill for HCPCS codes G2061–G2063 due to restrictions on their benefit category, nevertheless encouraged CMS to allow them to bill for these services.

Response: We thank commenters for submitting their comments. We note that a drafting error was made in the code descriptors for HCPCS codes G2061–G2063. The following are the correct descriptors:

- HCPCS code G2061 (*Qualified nonphysician healthcare professional online assessment and management, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*);
- HCPCS code G2062 (*Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*); and
- HCPCS code G2063 (*Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*).

We continue to believe that the work associated when these services are furnished by a nonphysician practitioner (NPP) will typically be less than when furnished by a physician, due to the acuity of the patient. Therefore, we maintain that HCPCS codes G2062 and G2063 are accurately valued at 0.44 and 0.69, respectively and are finalizing those values as proposed. We would also like to reiterate that there are many practitioners for whom these services fall outside the scope of their benefit category and as such, may not receive separate payment for these services under Medicare.

After consideration of the public comments we are finalizing as proposed.

(70) Emergency Department Visits (CPT Codes 99281, 99282, 99283, 99284, and 99285)

In the CY 2018 PFS final rule, we finalized a proposal to nominate CPT codes 99281–99285 as potentially misvalued based on information suggesting that the work RVUs for emergency department visits may not appropriately reflect the full resources involved in furnishing these services (FR 82 53018.) These five codes were surveyed and reviewed for the April 2018 RUC meeting. For CY 2020 we proposed the RUC-recommended work RVUs of 0.48 for CPT code 99281, a work RVU of 0.93 for CPT code 99282, a work RVU of 1.42 for 99283, a work RVU of 2.60 for 99284, and a work RVU of 3.80 for CPT code 99285.

The RUC did not recommend and we did not propose any direct PE inputs for the codes in this family.

We received public comments on the proposed valuation of the codes in the Emergency Department Visits family. The following is a summary of the comments we received and our responses.

Comment: Commenters from a major specialty society representing emergency department physicians suggested that, in order to maintain relativity with the newly revalued office/outpatient E/M visits, that CMS increase the work RVU to 1.60 for CPT code 99283, 2.74 for CPT code 99284, and 4.00 for CPT code 99285. Other commenters supported finalizing as proposed.

Response: We thank commenters for submitting their comments. As discussed in section II. P. of this final rule, Payment for Evaluation and Management Services, we are considering updating other E/M visits to maintain relativity with the revalued office/outpatient E/M code set as part of CY 2021 PFS rulemaking.

After consideration of the public comments, we are finalizing as proposed. We are also finalizing our proposal to have no direct PE inputs for these codes.

(71) Self-Measured Blood Pressure Monitoring (CPT Codes 99473, 99474, 93784, 93786, 93788, and 93790)

In September 2018, the CPT Editorial Panel created two new codes and revised four other codes to describe self-measured blood pressure monitoring services and to differentiate self-measured blood pressuring monitoring services from ambulatory blood pressure monitoring services. The first of the two new codes that describe self-measured blood pressure monitoring is CPT code 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*) and is a PE only code. The second code is 99474 (*Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings, one minute apart, twice daily over a 30-day period* (*minimum of 12 readings*), *collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average*

systolic and diastolic pressures and subsequent communication of a treatment plan to the patient).

The remaining four codes, which monitor ambulatory blood pressure, include CPT code 93784 (*Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report*), CPT code 93786 (*Ambulatory blood pressure monitoring, recording only*), CPT code 93788 (*Ambulatory blood pressure monitoring, scanning analysis with report*), and CPT code 93790 (*Ambulatory blood pressure monitoring, review with interpretation and report*). CPT code 93784 is a composite code that is the sum of CPT codes 93786, 93788, and 93790. CPT codes 93786 and 93788 are PE only codes.

We proposed the RUC-recommended work RVU of 0.18 for CPT code 99474, the RUC-recommended work RVU of 0.38 for CPT code 93784, and the RUC-recommended work RVU of 0.38 for CPT code 93790. We proposed the RUC-recommended work RVU of 0.00 for CPT codes 93786, 93788, and 99473. We also proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Self-Measured Blood Pressure Monitoring family. The following is a summary of the comments we received and our response.

Comment: Commenters expressed uniform support for the creation of self-measured blood pressure monitoring codes, as well as the proposed valuation of the codes.

Response: We are finalizing the work RVUs and direct PE inputs as proposed for CPT codes 99474, 93784, and 93790, as well as for CPT codes 93786, 93788, and 99473.

(72) Online Digital Evaluation Service (e-Visit) (CPT Codes 99421, 99422, and 99423)

In September 2018, the CPT Editorial Panel deleted two codes and replaced them with six new non-face-to face codes to describe patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office. The RUC reviewed and made recommendations for CPT code 99421 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes*), CPT code 99422 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes*), and CPT code 99423 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes*).

For CY 2020, we proposed the RUC-recommended work RVUs of 0.25 for CPT code 99421, 0.50 for CPT code 99422, and 0.80 for CPT code 99423. We proposed the RUC-recommended direct PE inputs for all codes in the family.

We received public comments on the proposed valuation of the codes in the Online Digital Evaluation Service (e-Visit) family. The following is a summary of the comments we received and our responses.

Comment: Commenters supported separate payment for these and the proposed values.

Response: We thank commenters for submitting their comments.

After consideration of the public comments we are finalizing as proposed.

(73) Radiation Therapy Codes (HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017)

For CY 2015, CPT revised the radiation therapy code set for following identification of some of the codes as potentially misvalued and the affected specialty society's contention that the provision of radiation therapy could not be accurately reported under the existing code set. In the CY 2015 PFS final rule, we finalized that we were delaying implementation of this revised code set, citing concerns with our potentially having finalized a substantial coding revision on an interim final basis. In addition, we stated that substantial work needed to be done to assure the new valuations for these codes accurately reflect the coding changes. We finalized that we would maintain inputs at CY 2014 levels by creating G-codes as necessary to allow practitioners to continue to report services to CMS in CY 2015 as they did in CY 2014 and for payments to be made in the same way. Following the publication of the CY 2015 PFS final rule, the Patient Access and Medicare Protection Act (Pub. L. 114–115, December 28, 2015) was enacted, which included the provision that the code definitions, the work relative value units and the direct inputs for the PE RVUs for radiation treatment delivery and related imaging services (identified in 2016 by HCPCS G-codes G6001 through G6015) for the fee schedule established under this subsection for services furnished in 2017 and 2018 shall be the same as such definitions, units, and inputs for such services for the fee schedule established for services furnished in 2016. In CY 2018, Congress extended this ''freeze'' in coding descriptions and inputs through CY 2019 as a provision of the Bipartisan Budget Act of 2018. For CY 2020, in the interest of payment stability, we proposed to continue using these G-codes, as well as their current work RVUs and direct PE inputs. We are also proposing that, for CY 2020, our PE methodology will continue to include a utilization rate assumption of 60 percent for the equipment item: ER089, ''IMRT Accelerator.''

We received public comments on the proposed valuation of the codes in the Radiation Therapy Codes family. The following is a summary of the comments we received and our responses.

Comment: Commenters stated that they support our proposals for these services.

Response: We appreciate the support for our proposal. After consideration of the public comments, we are finalizing our proposal to continue making payment for these services using HCPCS G-codes G6001 through G6017 with their current work RVUs and direct PE inputs.

Comment: A few commenters stated that we should develop RVUs for HCPCS code G6017 (*Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3d positional tracking, gating, 3d surface tracking)*), each fraction of treatment, which is a contractor priced code or its predecessor code CPT code 77387 (*Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed*), which has an inactive status. The commenters also requests that we publish RVUs for CPT code 77387 based on the RUC-recommended inputs submitted in 2014 despite this code having an inactive status for the benefit of third party payers to mitigate confusion and inconsistency.

Response: We continue to believe that, given the introduction of the Radiation Oncology Payment Model, it is preferable to maintain the current payment rates for these codes for CY 2020 in the interest of stability and to prevent disruption. We will, however, take this information into consideration for future rulemaking.

After consideration of the public comments, we are finalizing our proposal for these services.

(74) Immunization Administration Services (HCPCS Codes G0008, G0009, and G0010)

Recent epidemics, including the measles crisis earlier this year, emphasize the importance of consistent beneficiary access to vaccinations that are vital to public health. Medicare has established coding and payment for immunization administration services, including HCPCS codes G0008 (*Admin influenza virus vac*), G0009 (*Admin pneumococcal vaccine*), and G0010 (*Admin hepatitis b vaccine*) that allow for the vaccination of Medicare beneficiaries. While we did not make any specific proposals in the CY 2020 PFS proposed rule to change payment for these administration services, we did receive comments noting a decrease in payment for these services. These comments noted the linked crosswalk between CPT code 96372 *(Therapeutic, prophylactic, or diagnostic injection (specify substance or drug) subcutaneous or intramuscular)* and a number of the immunization services, and the impact that a proposed reduction to 96372 would have on payment for some practices that offer immunization services. We recognize that it is in the public interest to ensure appropriate payment to physicians and other practitioners for provision of the immunization administration services that are used to deliver vaccines and plan to review the valuations for these services to ensure appropriate payment. In the interim, given our concern about public access to vaccines and in light of recent public health events, we are maintaining the CY 2019 national payment amount for immunization administration services for CY 2020.

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TABLE 26: CY 2020 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
11981	Insertion, non-biodegradable drug delivery implant	1.48	1.14	1.14	No
11982	Removal, non-biodegradable drug delivery implant	1.78	1.34	1.34	No
11983	Removal with reinsertion, non-biodegradable drug delivery implant	3.30	1.91	1.91	No
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)	NEW	6.68	6.68	No
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate	NEW	6.73	6.73	No
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)	NEW	2.50	2.50	No
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate	NEW	6.83	6.83	No
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)	NEW	2.41	2.41	No
20220	Biopsy, bone, trocar, or needle; superficial (eg, ilium, sternum, spinous process, ribs)	1.27	1.65	1.65	No
20225	Biopsy, bone, trocar, or needle; deep (eg, vertebral body, femur)	1.87	2.45	2.45	No
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)	NEW	0.32	0.32	No
20561	Needle insertion(s) without injection(s); 3 or more muscles	NEW	0.48	0.48	No
20700	Manual preparation and insertion of drug-delivery device(s), deep (eg, subfascial) (List separately in addition to code for primary procedure)	NEW	1.32	1.50	No
20701	Removal of drug-delivery device(s), deep (eg, subfascial) (List separately in addition to code for primary procedure)	NEW	1.13	1.13	No
20702	Manual preparation and insertion of drug-delivery device(s), intramedullary (List separately in addition to code for primary procedure)	NEW	1.70	2.50	No
20703	Removal of drug-delivery device(s), intramedullary (List separately in addition to code for primary procedure)	NEW	1.80	1.80	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
20704	Manual preparation and insertion of drug-delivery device(s), intra-articular (List separately in addition to code for primary procedure)	NEW	1.80	2.60	No
20705	Removal of drug-delivery device(s), intra-articular (List separately in addition to code for primary procedure)	NEW	2.15	2.15	No
21601	Excision of chest wall tumor including rib(s)	NEW	17.78	17.78	No
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	NEW	22.19	22.19	No
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	NEW	25.17	25.17	No
22310	Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing	3.89	3.45	3.45	No
26020	Drainage of tendon sheath, digit and/or palm, each	5.08	6.84	6.84	No
26055	Tendon sheath incision (eg, for trigger finger)	3.11	3.11	3.11	No
26160	Excision of lesion of tendon sheath or joint capsule (eg, cyst, mucous cyst, or ganglion), hand or finger	3.57	3.57	3.57	No
27220	Closed treatment of acetabulum (hip socket) fracture(s); without manipulation	6.83	5.50	5.50	No
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	9.03	9.03	12.13	No
33016	Pericardiocentesis, including imaging guidance, when performed	NEW	4.40	4.40	No
33017	Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; 6 years and older without congenital cardiac anomaly	NEW	4.62	4.62	No
33018	Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; birth through 5 years of age or any age with congenital cardiac anomaly	NEW	5.00	5.40	No
33019	Pericardial drainage with insertion of indwelling catheter, percutaneous, including CT guidance	NEW	4.29	4.29	No
33020	Pericardiotomy for removal of clot or foreign body (primary procedure)	14.95	12.95	14.31	No
33025	Creation of pericardial window or partial resection for drainage	13.70	11.84	13.20	No
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	25.13	22.47	22.47	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	27.52	24.54	24.54	No
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	28.50	25.47	25.47	No
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	30.00	25.97	25.97	No
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)	33.12	26.59	26.59	No
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)	35.88	29.35	29.35	No
33858	Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic dissection	NEW	63.40	63.40	No
33859	Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic disease other than dissection (eg, aneurysm)	NEW	45.13	45.13	No
33863	Ascending aorta graft, with cardiopulmonary bypass, with aortic root replacement using valved conduit and coronary reconstruction (eg, Bentall)	58.79	58.79	58.79	No
33864	Ascending aorta graft, with cardiopulmonary bypass with valve suspension, with coronary reconstruction and valve-sparing aortic root remodeling (eg, David Procedure, Yacoub Procedure)	60.08	60.08	60.08	No
33866	Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)	19.74	17.75	17.75	No
33871	Transverse aortic arch graft, with cardiopulmonary bypass, with profound hypothermia, total circulatory arrest and isolated cerebral perfusion with reimplantation of arch vessel(s) (eg, island pedicle or individual arch vessel reimplantation)	NEW	60.88	60.88	No
34717	Endovascular repair of iliac artery at the time of aorto-iliac artery endograft placement by deployment of an iliac branched endograft including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all	NEW	9.00	9.00	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for rupture or other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer, traumatic disruption), unilateral (List separately in addition to code for primary procedure)				
34718	Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral	NEW	24.00	24.00	No
35701	Exploration not followed by surgical repair, artery; neck (eg, carotid, subclavian)	9.19	7.50	7.50	No
35702	Exploration not followed by surgical repair, artery; upper extremity (eg, axillary, brachial, radial, ulnar)	NEW	7.12	7.12	No
35703	Exploration not followed by surgical repair, artery; lower extremity (eg, common femoral, deep femoral, superficial femoral, popliteal, tibial, peroneal)	NEW	7.50	7.50	No
37252	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel (List separately in addition to code for primary procedure)	1.80	1.55	1.80	No
37253	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for primary procedure)	1.44	1.19	1.44	No
37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions	7.71	4.80	4.80	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions	9.66	6.00	6.00	No
40808	Biopsy, vestibule of mouth	1.01	1.01	1.05	No
46945	Hemorrhoidectomy, internal, by ligation other than rubber band; single hemorrhoid column/group, without imaging guidance	2.21	3.69	3.69	No
46946	Hemorrhoidectomy, internal, by ligation other than rubber band; 2 or more hemorrhoid columns/groups, without imaging guidance	2.63	4.50	4.50	No
46948	Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed	NEW	5.57	5.57	No
49013	Preperitoneal pelvic packing for hemorrhage associated with pelvic trauma, including local exploration	NEW	7.55	8.35	No
49014	Re-exploration of pelvic wound with removal of preperitoneal pelvic packing, including repacking, when performed	NEW	5.70	6.73	No
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant	4.50	4.00	4.00	No
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)	1.20	1.01	1.01	No
54640	Orchiopexy, inguinal or scrotal approach	7.73	7.73	7.73	No
62270	Spinal puncture, lumbar, diagnostic;	1.37	1.22	1.22	No
62272	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter);	1.35	1.58	1.58	No
62328	Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance	NEW	1.73	1.73	No
62329	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance	NEW	2.03	2.03	No
62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill	0.48	0.48	0.48	No
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming	0.67	0.67	0.67	No
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill	0.67	0.67	0.67	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)	0.90	0.90	0.90	No
64400	Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)	1.11	0.75	0.75	No
64408	Injection(s), anesthetic agent(s) and/or steroid; vagus nerve	1.41	0.75	0.75	No
64415	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus	1.48	1.35	1.35	No
64416	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement)	1.81	1.48	1.48	No
64417	Injection(s), anesthetic agent(s) and/or steroid; axillary nerve	1.44	1.27	1.27	No
64420	Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level	1.18	1.08	1.08	No
64421	Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, each additional level (List separately in addition to code for primary procedure)	1.68	0.50	0.50	No
64425	Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves	1.75	1.00	1.00	No
64430	Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve	1.46	1.00	1.00	No
64435	Injection(s), anesthetic agent(s) and/or steroid; paracervical (uterine) nerve	1.45	0.75	0.75	No
64445	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve	1.48	1.00	1.00	No
64446	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)	1.81	1.36	1.36	No
64447	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve	1.50	1.10	1.10	No
64448	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement)	1.63	1.41	1.41	No
64449	Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)	1.81	1.27	1.27	No
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch	0.75	0.75	0.75	No
64451	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	NEW	1.52	1.52	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	NEW	1.52	1.52	No
64624	Destruction by neurolytic agent, genicular nerve branches, including imaging guidance, when performed	NEW	2.50	2.50	No
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	NEW	3.39	3.39	No
64640	Destruction by neurolytic agent; other peripheral nerve or branch	1.23	1.98	1.98	No
66711	Ciliary body destruction; cyclophotocoagulation, endoscopic, without concomitant removal of crystalline lens	7.93	5.62	5.62	No
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation	11.08	10.25	10.25	No
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure)	10.43	C	C	No
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation	8.52	7.35	7.35	No
66987	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation	NEW	C	C	Yes
66988	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or	NEW	C	C	Yes

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	phacoemulsification); with endoscopic cyclophotocoagulation				
70210	Radiologic examination, sinuses, paranasal, less than 3 views	0.17	0.17	0.17	No
70220	Radiologic examination, sinuses, paranasal, complete, minimum of 3 views	0.25	0.22	0.22	No
70250	Radiologic examination, skull; less than 4 views	0.24	0.18	0.18	No
70260	Radiologic examination, skull; complete, minimum of 4 views	0.34	0.28	0.28	No
70360	Radiologic examination; neck, soft tissue	0.17	0.18	0.18	No
70480	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material	1.28	1.13	1.28	No
70481	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material(s)	1.38	1.06	1.13	No
70482	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material, followed by contrast material(s) and further sections	1.45	1.27	1.27	No
72020	Radiologic examination, spine, single view, specify level	0.15	0.16	0.16	No
72040	Radiologic examination, spine, cervical; 2 or 3 views	0.22	0.22	0.22	No
72050	Radiologic examination, spine, cervical; 4 or 5 views	0.31	0.27	0.27	No
72052	Radiologic examination, spine, cervical; 6 or more views	0.36	0.30	0.30	No
72070	Radiologic examination, spine; thoracic, 2 views	0.22	0.20	0.20	No
72072	Radiologic examination, spine; thoracic, 3 views	0.22	0.23	0.23	No
72074	Radiologic examination, spine; thoracic, minimum of 4 views	0.22	0.25	0.25	No
72080	Radiologic examination, spine; thoracolumbar junction, minimum of 2 views	0.22	0.21	0.21	No
72100	Radiologic examination, spine, lumbosacral; 2 or 3 views	0.22	0.22	0.22	No
72110	Radiologic examination, spine, lumbosacral; minimum of 4 views	0.31	0.26	0.26	No
72114	Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views	0.32	0.30	0.30	No
72120	Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views	0.22	0.22	0.22	No
72125	Computed tomography, cervical spine; without contrast material	1.07	1.00	1.00	No
72126	Computed tomography, cervical spine; with contrast material	1.22	1.22	1.22	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
72127	Computed tomography, cervical spine; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
72128	Computed tomography, thoracic spine; without contrast material	1.00	1.00	1.00	No
72129	Computed tomography, thoracic spine; with contrast material	1.22	1.22	1.22	No
72130	Computed tomography, thoracic spine; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
72131	Computed tomography, lumbar spine; without contrast material	1.00	1.00	1.00	No
72132	Computed tomography, lumbar spine; with contrast material	1.22	1.22	1.22	No
72133	Computed tomography, lumbar spine; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
72170	Radiologic examination, pelvis; 1 or 2 views	0.17	0.17	0.17	No
72190	Radiologic examination, pelvis; complete, minimum of 3 views	0.21	0.25	0.25	No
72200	Radiologic examination, sacroiliac joints; less than 3 views	0.17	0.17	0.17	No
72202	Radiologic examination, sacroiliac joints; 3 or more views	0.19	0.23	0.23	No
72220	Radiologic examination, sacrum and coccyx, minimum of 2 views	0.17	0.17	0.17	No
73000	Radiologic examination; clavicle, complete	0.16	0.16	0.16	No
73010	Radiologic examination; scapula, complete	0.17	0.17	0.17	No
73020	Radiologic examination, shoulder; 1 view	0.15	0.15	0.15	No
73030	Radiologic examination, shoulder; complete, minimum of 2 views	0.18	0.18	0.18	No
73050	Radiologic examination; acromioclavicular joints, bilateral, with or without weighted distraction	0.20	0.18	0.18	No
73070	Radiologic examination, elbow; 2 views	0.15	0.16	0.16	No
73080	Radiologic examination, elbow; complete, minimum of 3 views	0.17	0.17	0.17	No
73090	Radiologic examination; forearm, 2 views	0.16	0.16	0.16	No
73650	Radiologic examination; calcaneus, minimum of 2 views	0.16	0.16	0.16	No
73660	Radiologic examination; toe(s), minimum of 2 views	0.13	0.13	0.13	No
73700	Computed tomography, lower extremity; without contrast material	1.00	1.00	1.00	No
73701	Computed tomography, lower extremity; with contrast material(s)	1.16	1.16	1.16	No
73702	Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further sections	1.22	1.22	1.22	No
74210	Radiologic examination, pharynx and/or cervical esophagus, including scout neck	0.59	0.59	0.59	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	radiograph(s) and delayed image(s), when performed, contrast (eg, barium) study				
74220	Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	0.67	0.60	0.60	No
74221	Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; double-contrast (eg, high-density barium and effervescent agent) study	NEW	0.70	0.70	No
74230	Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (eg, barium) study	0.53	0.53	0.53	No
74240	Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	0.69	0.80	0.80	No
74246	Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (eg, high-density barium and effervescent agent) study, including glucagon, when administered	0.69	0.90	0.90	No
74248	Radiologic small intestine follow-through study, including multiple serial images (List separately in addition to code for primary procedure for upper GI radiologic exam)	NEW	0.70	0.70	No
74250	Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; single-contrast (eg, barium) study	0.47	0.81	0.81	No
74251	Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; double-contrast (eg, high-density barium and air via enteroclysis tube) study, including glucagon, when administered	0.69	1.17	1.17	No
74270	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	0.69	1.04	1.04	No
74280	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (eg, high density barium and air) study, including glucagon, when administered	0.99	1.26	1.26	No
74425	Urography, antegrade (pyelostogram, nephrostogram, loopogram), radiological supervision and interpretation	0.36	0.51	0.51	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
75625	Aortography, abdominal, by serialography, radiological supervision and interpretation	1.14	1.44	1.44	No
75630	Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation	1.79	2.00	2.00	No
75726	Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation	1.14	2.05	2.05	No
75774	Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (List separately in addition to code for primary procedure)	0.36	1.01	1.01	No
76098	Radiological examination, surgical specimen	0.16	0.31	0.31	No
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation	0.20	0.20	0.20	No
76604	Ultrasound, chest (includes mediastinum), real time with image documentation	0.55	0.59	0.59	No
77073	Bone length studies (orthoroentgenogram, scanogram)	0.27	0.26	0.26	No
77074	Radiologic examination, osseous survey; limited (eg, for metastases)	0.45	0.44	0.44	No
77075	Radiologic examination, osseous survey; complete (axial and appendicular skeleton)	0.54	0.55	0.55	No
77076	Radiologic examination, osseous survey, infant	0.70	0.70	0.70	No
77077	Joint survey, single view, 2 or more joints (specify)	0.31	0.33	0.33	No
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan	NEW	1.20	1.76	No
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	NEW	1.11	1.67	No
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic),	NEW	1.34	1.90	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	with concurrently acquired computed tomography transmission scan				
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	NEW	1.51	2.07	No
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	NEW	1.70	2.26	No
78434	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)	NEW	0.42	0.63	No
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study;	1.50	1.05	1.61	No
78491	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)	1.50	1.00	1.56	No
78492	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)	1.87	1.24	1.80	No
78800	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (eg, head, neck, chest, pelvis), single day of imaging	0.66	0.64	0.64	No
78801	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, 2 or more areas (eg, abdomen and pelvis, head and chest), 1 or more days of imaging or single area imaging over 2 or more days	0.79	0.73	0.73	No
78802	Radiopharmaceutical localization of tumor, inflammatory process or distribution of	0.86	0.80	0.80	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, whole body, single day imaging				
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis), single day of imaging	1.09	1.09	1.09	No
78804	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, whole body, requiring 2 or more days imaging	1.07	1.01	1.01	No
78830	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis), single day of imaging	NEW	1.49	1.49	No
78831	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days	NEW	1.82	1.82	No
78832	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days imaging	NEW	2.12	2.12	No
78835	Radiopharmaceutical quantification measurement(s) single area	NEW	0.47	0.47	No
88141	Cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician	0.42	0.26	0.26	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient	NEW	0.90	0.90	No
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)	NEW	0.50	0.50	No
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	0.17	0.10	0.10	No
92201	Ophthalmoscopy, extended; with retinal drawing and scleral depression, of peripheral retinal disease (eg, for retinal tear, retinal detachment, retinal tumor) with interpretation and report, unilateral or bilateral	NEW	0.40	0.40	No
92202	Ophthalmoscopy, extended; with drawing of optic nerve or macula (eg, for glaucoma, macular pathology, tumor) with interpretation and report, unilateral or bilateral	NEW	0.26	0.26	No
92548	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report;	0.50	0.67	0.67	No
92549	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT)	NEW	0.87	0.87	No
92626	Evaluation of auditory function for surgically implanted device(s) candidacy or post-operative status of a surgically implanted device(s); first hour	1.40	1.40	1.40	No
92627	Evaluation of auditory function for surgically implanted device(s) candidacy or post-operative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)	0.33	0.33	0.33	No
92992	Atrial septectomy or septostomy; transvenous method, balloon (eg, Rashkind type) (includes cardiac catheterization)	C	C	C	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
92993	Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)	C	C	C	No
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
93356	Myocardial strain imaging using speckle–tracking derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)	NEW	0.24	0.24	No
93784	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report	0.38	0.38	0.38	No
93786	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; recording only	0.00	0.00	0.00	No
93788	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; scanning analysis with report	0.00	0.00	0.00	No
93790	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; review with interpretation and report	0.38	0.38	0.38	No
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	NEW	0.80	0.80	No
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	NEW	0.50	0.50	No
94200	Maximum breathing capacity, maximal voluntary ventilation	0.11	0.05	0.05	No
95700	Electroencephalogram (EEG) continuous recording, with video when performed, setup, patient education, and takedown when	NEW	0.00	0.00	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	performed, administered in person by EEG technologist, minimum of 8 channels				
95705	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; unmonitored	NEW	0.00	0.00	No
95706	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95707	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95708	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored	NEW	0.00	0.00	No
95709	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95710	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95711	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; unmonitored	NEW	0.00	0.00	No
95712	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95713	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95714	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored	NEW	0.00	0.00	No
95715	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95716	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95717	Electroencephalogram, continuous recording, physician or other qualified health care	NEW	1.85	2.00	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	professional review of recorded events, analysis of spike and seizure detection, interpretation and report, 2-12 hours of EEG recording; without video				
95718	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation and report, 2-12 hours of EEG recording; with video (VEEG)	NEW	2.35	2.50	No
95719	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; without video	NEW	2.60	3.00	No
95720	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; with video (VEEG)	NEW	3.50	3.86	No
95721	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, without video	NEW	3.86	3.86	No
95722	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, with video (VEEG)	NEW	4.70	4.70	No
95723	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 60 hours, up to 84 hours of EEG recording, without video	NEW	4.75	4.75	No
95724	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete	NEW	6.00	6.00	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	study; greater than 60 hours, up to 84 hours of EEG recording, with video (VEEG)				
95725	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, without video	NEW	5.40	5.40	No
95726	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, with video (VEEG)	NEW	7.58	7.58	No
96156	Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)	NEW	2.10	2.10	No
96158	Health behavior intervention, individual, face-to-face; initial 30 minutes	NEW	1.45	1.45	No
96159	Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.50	0.50	No
96164	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes	NEW	0.21	0.21	No
96165	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.10	0.10	No
96167	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes	NEW	1.55	1.55	No
96168	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.55	0.55	No
96170	Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes	NEW	1.50	1.50	No
96171	Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.54	0.54	No
97129	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time	NEW	0.50	0.50	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes				
97130	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	0.48	0.48	No
97597	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less	0.51	0.77	0.77	No
97598	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)	0.24	0.50	0.50	No
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters	C	0.41	0.41	No
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s)	C	0.46	0.46	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	surface area greater than 50 square centimeters				
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	0.35	0.40	0.40	No
98970	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes	NEW	I	I	Yes
98971	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes	NEW	I	I	Yes
98972	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes	NEW	I	I	Yes
99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor.	0.45	0.48	0.48	No
99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.	0.88	0.93	0.93	No
99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity.	1.34	1.42	1.42	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.				
99284	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.	2.56	2.60	2.60	No
99285	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.	3.80	3.80	3.80	No
99421	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	NEW	0.25	0.25	No
99422	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	NEW	0.50	0.50	No
99423	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes	NEW	0.80	0.80	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)	NEW	0.50	0.61	No
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration	NEW	0.00	0.00	No
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient	NEW	0.18	0.18	No
99495	Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of at least moderate complexity during the service period Face-to-face visit, within 14 calendar days of discharge	2.11	2.36	2.36	No
99496	Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of high complexity during the service period Face-to-face visit, within 7 calendar days of discharge	3.05	3.10	3.10	No
G0124	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician	0.42	0.26	0.26	No
G0141	Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician	0.42	0.26	0.26	No
G2058	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	NEW	0.54	0.54	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	(List separately in addition to code for primary procedure). (Do not report G2058 for care management services of less than 20 minutes additional to the first 20 minutes of chronic care management services during a calendar month). (Use G2058 in conjunction with 99490). (Do not report 99490, G2058 in the same calendar month as 99487, 99489, 99491)).				
G2061	Qualified nonphysician healthcare professional online assessment and management, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes	NEW	0.25	0.25	No
G2062	Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes	NEW	0.44	0.44	No
G2063	Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes	NEW	0.69	0.69	No
G2064	Comprehensive care management services for a single high-risk disease, e.g., Principal Care Management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities	NEW	1.28	1.45	No
G2065	Comprehensive care management for a single high-risk disease services, e.g. Principal Care Management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: one complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires	NEW	0.61	0.61	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities				
G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	NEW	0.00	0.00	No
G2067	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW	0.00	0.00	No
G2068	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW	0.00	0.00	No
G2069	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW	0.00	0.00	No
G2070	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW	0.00	0.00	No
G2071	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW	0.00	0.00	No
G2072	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology	NEW	0.00	0.00	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)				
G2073	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW	0.00	0.00	No
G2074	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW	0.00	0.00	No
G2075	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW	C	C	No
G2076	Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician qualified personnel that includes preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho- social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	0.00	0.00	No
G2077	Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	0.00	0.00	No
G2078	Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid	NEW	0.00	0.00	No

HCPCS	Descriptor	CY 2019 Work RVU	Proposed CY 2020 Work RVU	Final CY 2020 Work RVU	CMS Work Time Refinement
	Treatment Program); List separately in addition to code for primary procedure.				
G2079	Take-home supply of buprenorphine (oral); up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	0.00	0.00	No
G2080	Each additional 30 minutes of counseling in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	0.00	0.00	No
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.	NEW	-	0.48	No
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.	NEW	-	0.48	No
G2086	Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.	NEW	7.06	7.06	No
G2087	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.	NEW	6.89	6.89	No
G2088	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes	NEW	0.82	0.82	No
P3001	Screening papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician	0.42	0.26	0.26	No

TABLE 27: CY 2020 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
20225	Bone biopsy trocar/needle	SC077	needle, bone biopsy	NF		0	1	S8: Supply item replaces another item; see preamble SF055	68.50
20225	Bone biopsy trocar/needle	SF055	Bone biopsy device	NF		1	0	S7: Supply item replaced by another item; see preamble SC077	-158.43
22310	Closed tx vert fx w/o manj	EF031	table, power	NF		106	108	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
27220	Treat hip socket fracture	EF031	table, power	NF		101	103	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
33859	As-aort grf f/ds oth/thn dsj	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
33863	Ascending aortic graft	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
33864	Ascending aortic graft	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
33871	Transvrs a-arch grf hypthrm	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
35701	Exploration carotid artery	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	36	27	L9: Refined clinical labor to align with number of post-operative visits	-3.33
35702	Expl n/flwd surg uxtr art	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	36	27	L9: Refined clinical labor to align with number of post-operative visits	-3.33

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
35703	Expl n/flwd surg lxtr art	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	63	27	L9: Refined clinical labor to align with number of post-operative visits	-13.32
35703	Expl n/flwd surg lxtr art	SA048	pack, minimum multi-specialty visit	F		2	1	S13: Refined supply quantity to align with number of post-operative visits	-3.08
40808	Biopsy of mouth lesion	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		17	29	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
40808	Biopsy of mouth lesion	L037D	RN/LPN/MTA	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.37
40808	Biopsy of mouth lesion	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	2	3	G1: See preamble text	0.37
62370	Anl sp inf pmp w/mdreprg&fil	SA048	pack, minimum multi-specialty visit	NF		1	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-3.08
64400	Njx aa&/strd trigeminal nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64408	Njx aa&/strd vagus nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64415	Njx aa&/strd brach plexus	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64417	Njx aa&/strd axillary nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64420	Njx aa&/strd ntrcost nrv 1	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64425	Njx aa&/strd ii ih nerves	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64430	Njx aa&/strd pudendal nerve	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64435	Njx aa&/strd paracrv nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64445	Njx aa&/strd sciatic nerve	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64447	Njx aa&/strd femoral nerve	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64450	Njx aa&/strd other pn/branch	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (100% of physician intra-service time)	10	5	L15: Refined clinical labor time to match intraservice work time	-1.85
64450	Njx aa&/strd other pn/branch	L037D	RN/LPN/MTA	F	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
64450	Njx aa&/strd other pn/branch	L037D	RN/LPN/MTA	NF	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
64451	Njx aa&/strd nrv nrvtg si jt	ED050	Technologist PACS workstation	NF		36	41	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
64451	Njx aa&/strd nrv nrvtg si jt	SC028	needle, 18-26g 1.5-3.5in, spinal	NF		3	4	G1: See preamble text	6.64
64625	Rf abltj nrv nrvtg si jt	ED050	Technologist PACS workstation	NF		51	56	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
64640	Injection treatment of nerve	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time	25	20	L15: Refined clinical labor time to match intraservice work time	-1.85

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					(100% of physician intra-service time)				
64640	Injection treatment of nerve	L037D	RN/LPN/MTA	F	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
64640	Injection treatment of nerve	L037D	RN/LPN/MTA	NF	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
66987	Xcapsl ctrc rmvl cplx w/ecp	EL005	lane, exam (oph)	F		180	0	G1: See preamble text	-21.01
66987	Xcapsl ctrc rmvl cplx w/ecp	EL006	lane, screening (oph)	F		27	0	G1: See preamble text	-3.06
66987	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/RN/CST	F	Schedule space and equipment in facility	8	0	G1: See preamble text	-3.04
66987	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/RN/CST	F	Coordinate pre-surgery services (including test results)	20	0	G1: See preamble text	-7.60
66987	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/RN/CST	F	Discharge day management	6	0	G1: See preamble text	-2.28
66987	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/RN/CST	F	Complete pre-procedure phone calls and prescription	7	0	G1: See preamble text	-2.66
66987	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/RN/CST	F	Complete pre-service diagnostic and referral forms	5	0	G1: See preamble text	-1.90
66987	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/RN/CST	F	Post-operative visits (total time)	207	0	G1: See preamble text	-78.66
66987	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/RN/CST	F	Provide pre-service education/obtain consent	20	0	G1: See preamble text	-7.60
66987	Xcapsl ctrc rmvl cplx w/ecp	SA050	pack, ophthalmology visit (no dilation)	F		1	0	G1: See preamble text	-1.95
66987	Xcapsl ctrc rmvl cplx w/ecp	SA082	pack, ophthalmology visit (w-dilation)	F		5	0	G1: See preamble text	-14.77
66988	Xcapsl ctrc rmvl w/ecp	EL005	lane, exam (oph)	F		144	0	G1: See preamble text	-16.81

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
66988	Xcapsl ctrc rmvl w/ecp	EL006	lane, screening (oph)	F		27	0	G1: See preamble text	-3.06
66988	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Schedule space and equipment in facility	8	0	G1: See preamble text	-3.04
66988	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Provide pre-service education/obtain consent	20	0	G1: See preamble text	-7.60
66988	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Discharge day management	6	0	G1: See preamble text	-2.28
66988	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Post-operative visits (total time)	171	0	G1: See preamble text	-64.98
66988	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Complete pre-service diagnostic and referral forms	5	0	G1: See preamble text	-1.90
66988	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Complete pre-procedure phone calls and prescription	7	0	G1: See preamble text	-2.66
66988	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Coordinate pre-surgery services (including test results)	20	0	G1: See preamble text	-7.60
66988	Xcapsl ctrc rmvl w/ecp	SA050	pack, ophthalmology visit (no dilation)	F		1	0	G1: See preamble text	-1.95
66988	Xcapsl ctrc rmvl w/ecp	SA082	pack, ophthalmology visit (w-dilation)	F		4	0	G1: See preamble text	-11.81
70210	X-ray exam of sinuses	ED050	Technologist PACS workstation	NF		13	18	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
70220	X-ray exam of sinuses	ED050	Technologist PACS workstation	NF		16	21	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
74250	X-ray exam of small bowel	EL014	room, radiographic-fluoroscopic	NF		29	26	E2: Refined equipment time to conform to established policies for highly technical equipment	-5.94

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
78800	Rp loclzj tum 1 area 1 d img	ED050	Technologist PACS workstation	NF		64	62	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
78801	Rp loclzj tum 2+area 1+d img	ED050	Technologist PACS workstation	NF		75	73	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
78802	Rp loclzj tum whbdy 1 d img	ED050	Technologist PACS workstation	NF		85	83	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
78803	Rp loclzj tum spect 1 area	ED050	Technologist PACS workstation	NF		103	101	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
78803	Rp loclzj tum spect 1 area	ED053	Professional PACS Workstation	NF		30	27	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
78804	Rp loclzj tum whbdy 2+d img	ED050	Technologist PACS workstation	NF		185	183	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
78804	Rp loclzj tum whbdy 2+d img	ED053	Professional PACS Workstation	NF		23	20	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
78830	Rp loclzj tum spect w/ct 1	ED050	Technologist PACS workstation	NF		114	112	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
78830	Rp loclzj tum spect w/ct 1	ED053	Professional PACS Workstation	NF		33	30	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
78831	Rp loclzj tum spect 2 areas	ED050	Technologist PACS workstation	NF		194	192	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
78831	Rp loclzj tum spect 2 areas	ED053	Professional PACS Workstation	NF		38	35	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
78832	Rp loclzj tum spect w/ct 2	ED050	Technologist PACS workstation	NF		227	225	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
78832	Rp loclzj tum spect w/ct 2	ED053	Professional PACS Workstation	NF		43	40	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
88141	Cytopath c/v interpret	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
88141	Cytopath c/v interpret	L045A	Cytotechnologist	NF	Perform regulatory mandated quality assurance activity (service period)	7	5	G1: See preamble text	-0.90
90912	Bfb training 1st 15 min	EF031	table, power	NF		31	29	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
93297	Icm device interrogat remote	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		40	0	G1: See preamble text	-18.51
93297	Icm device interrogat remote	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	40	0	G1: See preamble text	-14.80
93297	Icm device interrogat remote	SK057	paper, laser printing (each sheet)	NF		10	0	G1: See preamble text	-0.13
93298	Ilr device interrogat remote	EQ198	pacemaker follow-up system (incl software	NF		76	0	G1: See preamble text	-35.17

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			and hardware) (Paceart)						
93298	Ilr device interrogat remote	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	76	0	G1: See preamble text	-28.12
93298	Ilr device interrogat remote	SK057	paper, laser printing (each sheet)	NF		10	0	G1: See preamble text	-0.13
93299	Icm/ilr remote tech serv	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		76	0	G1: See preamble text	-35.17
93299	Icm/ilr remote tech serv	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	76	0	G1: See preamble text	-28.12
93299	Icm/ilr remote tech serv	SK057	paper, laser printing (each sheet)	NF		10	0	G1: See preamble text	-0.13
93985	Dup-scan hemo compl bi std	L054A	Vascular Technologist	NF	Prepare room, equipment and supplies	4	2	L1: Refined time to standard for this clinical labor task	-1.08
93986	Dup-scan hemo compl uni std	L054A	Vascular Technologist	NF	Prepare room, equipment and supplies	4	2	L1: Refined time to standard for this clinical labor task	-1.08
95717	Eeg phys/qhp 2-12 hr w/o vid	EQ016	EEG review station, ambulatory	NF		48	32	G1: See preamble text	-0.50
95718	Eeg phys/qhp 2-12 hr w/veeg	EQ016	EEG review station, ambulatory	NF		55	40	G1: See preamble text	-0.47
95719	Eeg phys/qhp ea incr w/o vid	EQ016	EEG review station, ambulatory	NF		60	45	G1: See preamble text	-0.47
95720	Eeg phy/qhp ea incr w/veeg	EQ016	EEG review station, ambulatory	NF		75	60	G1: See preamble text	-0.47
95721	Eeg phy/qhp>36<60 hr w/o vid	EQ016	EEG review station, ambulatory	NF		85	70	G1: See preamble text	-0.47

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
95722	Eeg phy/qhp>36<60 hr w/veeg	EQ016	EEG review station, ambulatory	NF		100	85	G1: See preamble text	-0.47
95723	Eeg phy/qhp>60<84 hr w/o vid	EQ016	EEG review station, ambulatory	NF		110	95	G1: See preamble text	-0.47
95724	Eeg phy/qhp>60<84 hr w/veeg	EQ016	EEG review station, ambulatory	NF		130	115	G1: See preamble text	-0.47
95725	Eeg phy/qhp>84 hr w/o vid	EQ016	EEG review station, ambulatory	NF		130	115	G1: See preamble text	-0.47
95726	Eeg phy/qhp>84 hr w/veeg	EQ016	EEG review station, ambulatory	NF		160	145	G1: See preamble text	-0.47
97607	Neg press wnd tx </=50 sq cm	L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	L1: Refined time to standard for this clinical labor task	-1.11
97608	Neg press wound tx >50 cm	L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	L1: Refined time to standard for this clinical labor task	-1.11
G0124	Screen c/v thin layer by md	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
G0124	Screen c/v thin layer by md	L045A	Cytotechnologist	NF	Perform regulatory mandated quality assurance activity (service period)	7	5	G1: See preamble text	-0.90
G0141	Scr c/v cyto,autosys and md	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
G0141	Scr c/v cyto,autosys and md	L045A	Cytotechnologist	NF	Perform regulatory mandated quality	7	5	G1: See preamble text	-0.90

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					assurance activity (service period)				
P3001	Screening pap smear by phys	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
P3001	Screening pap smear by phys	L045A	Cytotechnologist	NF	Perform regulatory mandated quality assurance activity (service period)	7	5	G1: See preamble text	-0.90

TABLE 28: CY 2020 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
35701	Exploration carotid artery	EF023	table, exam	F		36	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
35702	Expl n/flwd surg uxtr art	EF023	table, exam	F		36	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
35703	Expl n/flwd surg lxtr art	EF023	table, exam	F		63	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.24
64400	Njx aa&/strd trigeminal nrv	EF015	mayo stand	NF		25	24	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64400	Njx aa&/strd trigeminal nrv	EF023	table, exam	NF		25	24	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64408	Njx aa&/strd vagus nrv	EF008	chair with headrest, exam, reclining	NF		20	19	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64408	Njx aa&/strd vagus nrv	EF015	mayo stand	NF		20	19	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64415	Njx aa&/strd brach plexus	EF015	mayo stand	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64415	Njx aa&/strd brach plexus	EF023	table, exam	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64415	Njx aa&/strd brach plexus	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		84	83	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64417	Njx aa&/strd axillary nrv	EF015	mayo stand	NF		22	21	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64417	Njx aa&/strd axillary nrv	EF023	table, exam	NF		22	21	E15: Refined equipment time to conform to changes in clinical labor time	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64417	Njx aa&/strd axillary nrv	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		82	81	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64420	Njx aa&/strd ntrcost nrv 1	EF015	mayo stand	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64420	Njx aa&/strd ntrcost nrv 1	EF023	table, exam	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64420	Njx aa&/strd ntrcost nrv 1	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		89	88	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64425	Njx aa&/strd ii ih nerves	EF015	mayo stand	NF		30	29	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64425	Njx aa&/strd ii ih nerves	EF023	table, exam	NF		30	29	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64425	Njx aa&/strd ii ih nerves	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		90	89	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64430	Njx aa&/strd pudendal nerve	EF023	table, exam	NF		28	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64430	Njx aa&/strd pudendal nerve	EF027	table, instrument, mobile	NF		28	27	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64430	Njx aa&/strd pudendal nerve	EQ168	light, exam	NF		28	27	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64435	Njx aa&/strd paracrv nrv	EF023	table, exam	NF		23	22	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64435	Njx aa&/strd paracrv nrv	EF027	table, instrument, mobile	NF		23	22	E15: Refined equipment time to conform to changes in clinical labor time	0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64435	Njx aa&/strd paracrv nrv	EQ168	light, exam	NF		23	22	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64445	Njx aa&/strd sciatic nerve	EF015	mayo stand	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64445	Njx aa&/strd sciatic nerve	EF023	table, exam	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64445	Njx aa&/strd sciatic nerve	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		89	88	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64445	Njx aa&/strd sciatic nerve	EQ184	nerve stimulator (eg, for nerve block)	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64447	Njx aa&/strd femoral nerve	EF015	mayo stand	NF		18	17	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64447	Njx aa&/strd femoral nerve	EF023	table, exam	NF		18	17	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64447	Njx aa&/strd femoral nerve	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		78	77	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64450	Njx aa&/strd other pn/branch	EF015	mayo stand	NF		29	24	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64450	Njx aa&/strd other pn/branch	EF023	table, exam	NF		29	24	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
64450	Njx aa&/strd other pn/branch	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		89	84	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
64640	Injection treatment of nerve	EF015	mayo stand	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64640	Injection treatment of nerve	EF031	table, power	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
64640	Injection treatment of nerve	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		64	59	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
64640	Injection treatment of nerve	EQ168	light, exam	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
64640	Injection treatment of nerve	EQ184	nerve stimulator (eg, for nerve block)	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64640	Injection treatment of nerve	EQ214	radiofrequency generator (NEURO)	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.68
64640	Injection treatment of nerve	EQ354	radiofrequency kit for destruction by neurolytic agent	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.20
93985	Dup-scan hemo compl bi std	ED050	Technologist PACS workstation	NF		101	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
93985	Dup-scan hemo compl bi std	EL016	room, ultrasound, vascular	NF		86	84	E15: Refined equipment time to conform to changes in clinical labor time	-3.57
93986	Dup-scan hemo compl uni std	ED050	Technologist PACS workstation	NF		60	58	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
93986	Dup-scan hemo compl uni std	EL016	room, ultrasound, vascular	NF		47	45	E15: Refined equipment time to conform to changes in clinical labor time	-3.57
97607	Neg press wnd tx </=50 sq cm	EF014	light, surgical	NF		23	20	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
97607	Neg press wnd tx </=50 sq cm	EF031	table, power	NF		23	20	E15: Refined equipment time to conform to changes in clinical labor time	-0.05

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97608	Neg press wound tx >50 cm	EF014	light, surgical	NF		31	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
97608	Neg press wound tx >50 cm	EF031	table, power	NF		31	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.05

TABLE 29: CY 2020 Invoices Received for Existing Direct PE Inputs

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
52441, 52442	Urolift Implant and implantation device	SD291	$814.89	$875.00	7%	3	24,149
78072, 78830, 78832, 78835	gamma camera system, single-dual head SPECT CT	ER097	$464,428.95	$703,443.37	51%	5	4,334
92546, 92548, 92549	CDP-computerized dynamic posturography system	EQ002	$68,842.62	$86,334.50	25%	6	80,359

TABLE 30: CY 2020 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
15771, 15773	Liposuction system	EQ395	22,039.05	1	1,565
20560, 20561	needle, dry needling	SC107	0.25	3	8
37765, 37766	tumescent tubing	SD333	11.00	3	18,700
37765, 37766	tumescent pump	EQ393	1,750.00	1	18,700
64430, 64435	pudendal block tray, sterile	SA129	5.24	1	1,254
78434	Software and hardware package for Absolute Quantitation	ER113	44,652.33	6	157
78459, 78491, 78492, 78432	PET Refurbished Imaging Cardiac Configuration	ER110	527,615.63	10	65,277
78491, 78492, 78430, 78431, 78432, 78433	IV line kit for Rb Generator	SA130	16.98	7	130,539
78491, 78492, 78430, 78431, 78432, 78433, 78434	PET Generator (Rubidium)	ER114	47,052.80	5	130,696
78491, 78492, 78430, 78431, 78432, 78433, 78434	PET Infusion Cart	ER109	74,225.47	4	130,696
78429, 78430, 78431, 78433, 78434	PET/CT Imaging Camera Cardiac Configuration	ER111	1,364,960.59	8	65,798
78835	Software and hardware package for tumor and other distribution Quantitation	ER112	40,535.75	4	23
95700, 95714, 95715, 95716	EEG, digital, prolonged testing system with remote video, for patients home use	EQ394	29,496.98	3	251,218
97607, 97608	kit, negative pressure wound therapy, disposable	SA131	208.00	12	759

TABLE 31: CY 2020 No PE Refinements

HCPCS	Description
11981	Insert drug implant device
11982	Remove drug implant device
11983	Remove/insert drug implant
15769	grfg autol soft tiss dir exc
15771	grfg autol fat lipo 50 cc/<
15772	grfg autol fat lipo ea addl
15773	grfg autol fat lipo 25 cc/<
15774	gfrg autol fat lipo ea addl
20220	Bone biopsy trocar/needle
20560	Ndl insj w/o njx 1 or 2 musc
20561	Ndl insj w/o njx 3+ musc
20700	Mnl prep&insj dp rx dlvr dev
20701	Rmvl deep rx delivery device
20702	Mnl prep&insj imed rx dev
20703	Rmvl imed rx delivery device
20704	Mnl prep&insj i-artic rx dev
20705	Rmvl i-artic rx delivery dev
26020	Drain hand tendon sheath
26055	Incise finger tendon sheath
26160	Remove tendon sheath lesion
27279	Arthrodesis sacroiliac joint
33020	Incision of heart sac
33025	Incision of heart sac
33361	Replace aortic valve perq
33362	Replace aortic valve open
33363	Replace aortic valve open
33364	Replace aortic valve open
33365	Replace aortic valve open
33366	Trcath replace aortic valve
33858	As-aort grf f/aortic dsj
33866	Aortic hemiarch graft
34718	Evasc rpr n/a a-iliac ndgft
37252	Intrvasc us noncoronary 1st
37253	Intrvasc us noncoronary addl
37765	Stab phleb veins xtr 10-20
37766	Phleb veins - extrem 20+
46945	Int hrhc lig 1 hroid w/o img
46946	Int hrhc lig 2+hroid w/o img
46948	Int hrhc tranal dartlzj 2+
49014	Reexploration pelvic wound
52441	Cystourethro w/implant
52442	Cystourethro w/addl implant
54640	Orchiopexy ingun/scrot appr
62270	Dx lmbr spi pnxr
62272	Ther spi pnxr drg csf
62328	Dx lmbr spi pnxr w/fluor/ct
62329	Ther spi pnxr csf fluor/ct
62367	Analyze spine infus pump
62368	Analyze sp inf pump w/reprog
62369	Anal sp inf pmp w/reprg&fill

HCPCS	Description
64421	Njx aa&/strd ntrcost nrv ea
64449	Njx aa&/strd lmbr plex nfs
64454	Njx aa&/strd gnclr nrv brnch
64624	Dstrj nulyt agt gnclr nrv
66711	Ecp ciliary body destruction
66982	Xcapsl ctrc rmvl cplx wo ecp
66984	Xcapsl ctrc rmvl w/o ecp
70210	X-ray exam of sinuses
70220	X-ray exam of sinuses
70250	X-ray exam of skull
70260	X-ray exam of skull
70360	X-ray exam of neck
70480	Ct orbit/ear/fossa w/o dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o&w/dye
72020	X-ray exam of spine 1 view
72040	X-ray exam neck spine 2-3 vw
72050	X-ray exam neck spine 4/5vws
72052	X-ray exam neck spine 6/>vws
72070	X-ray exam thorac spine 2vws
72072	X-ray exam thorac spine 3vws
72074	X-ray exam thorac spine4/>vw
72080	X-ray exam thoracolmb 2/> vw
72100	X-ray exam l-s spine 2/3 vws
72110	X-ray exam l-2 spine 4/>vws
72114	X-ray exam l-s spine bending
72120	X-ray bend only l-s spine
72125	Ct neck spine w/o dye
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72128	Ct chest spine w/o dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72131	Ct lumbar spine w/o dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72170	X-ray exam of pelvis
72190	X-ray exam of pelvis
72200	X-ray exam si joints
72202	X-ray exam si joints 3/> vws
72220	X-ray exam sacrum tailbone
73000	X-ray exam of collar bone
73010	X-ray exam of shoulder blade
73020	X-ray exam of shoulder
73030	X-ray exam of shoulder
73050	X-ray exam of shoulders
73070	X-ray exam of elbow
73080	X-ray exam of elbow
73090	X-ray exam of forearm
73650	X-ray exam of heel

HCPCS	Description
73660	X-ray exam of toe(s)
73700	Ct lower extremity w/o dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o&w/dye
74210	X-ray xm phrnx&/crv esoph c+
74220	X-ray xm esophagus 1cntrst
74221	X-ray xm esophagus 2cntrst
74230	X-ray xm swlng funcj c+
74240	X-ray xm upr gi trc 1cntrst
74246	X-ray xm upr gi trc 2cntrst
74248	X-ray sm int f-thru std
74251	X-ray exam of small bowel
74270	X-ray xm colon 1cntrst std
74280	X-ray xm colon 2cntrst std
74425	Contrst x-ray urinary tract
75625	Contrast exam abdominl aorta
75630	X-ray aorta leg arteries
75726	Artery x-rays abdomen
75774	Artery x-ray each vessel
76098	X-ray exam breast specimen
76376	3d render w/intrp postproces
76604	Us exam chest
77073	X-rays bone length studies
77074	X-rays bone survey limited
77075	X-rays bone survey complete
77076	X-rays bone survey infant
77077	Joint survey single view
78835	Rp quan meas single area
90913	Bfb training ea addl 15 min
92145	Corneal hysteresis deter
92201	Opscpy extnd rta draw uni/bi
92202	Opscpy extnd on/mac draw
92548	Cdp-sot 6 cond w/i&r
92549	Cdp-sot 6 cond w/i&r mct&adt
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
93356	Myocrd strain img spckl trck
93784	Ambl bp mntr w/software
93786	Ambl bp mntr w/sw rec only
93788	Ambl bp mntr w/sw a/r
93790	Ambl bp mntr w/sw i&r
94200	Lung function test (mbc/mvv)
96156	Hlth bhv assmt/reassessment
96158	Hlth bhv ivntj indiv 1st 30
96159	Hlth bhv ivntj indiv ea addl
96164	Hlth bhv ivntj grp 1st 30
96165	Hlth bhv ivntj grp ea addl
96167	Hlth bhv ivntj fam 1st 30
96168	Hlth bhv ivntj fam ea addl
96170	Hlth bhv ivntj fam wo pt 1st
96171	Hlth bhv ivntj fam w/o pt ea
97129	Ther ivntj 1st 15 min
97130	Ther ivntj ea addl 15 min
97597	Rmvl devital tis 20 cm/<
97598	Rmvl devital tis addl 20cm/<
97610	Low frequency non-thermal us
98970	Qnhp ol dig e/m svc 5-10min
98971	Qnhp ol dig em svc 11-20min
98972	Qnhp ol dig e/m svc 21+ min
99421	Ol dig e/m svc 5-10 min
99422	Ol dig e/m svc 11-20 min
99423	Ol dig e/m svc 21+ min
99458	Rem physiol mntr ea addl 20
99473	Self-meas bp pt educaj/train
99474	Self-meas bp 2 readg bid 30d
99495	Trans care mgmt 14 day disch
99496	Trans care mgmt 7 day disch
G2061	Qual nonMD est pt 5-10m
G2062	Qual nonMD est pt 11-20m
G2063	Qual nonMD est pt 21>min

O. Response to the Comment Solicitation on Opportunities for Bundled Payments Under the PFS

Under the PFS, Medicare typically makes a separate payment for each individual service furnished to a beneficiary consistent with section 1848 of the Act, which requires CMS to establish payment for physicians' services based on the relative resources involved in furnishing the service. The statute defines ''services'' broadly, with reference to the uniform procedure coding system established by CMS for the purpose of Medicare FFS payments, called the Healthcare Common Procedure Coding System (HCPCS). There are sets of HCPCS codes that represent health care procedures, supplies, medical equipment, products, and services. The majority of physicians' services for which payment is made under the PFS are described using HCPCS Level I codes and descriptors that are the AMA's Current Procedural Terminology (CPT) code set. CPT codes generally describe an individual item or service, while some codes describe a combination of services (a procedure and imaging guidance, for example) bundled together. Some HCPCS codes explicitly encompass multiple services (global surgery codes, for example), and the PFS payment for some services is reduced when a combination of services is furnished to the same patient on the same day (through multiple procedure payment reduction policies). However, payment for most services under the PFS is made based on rates established for individual services, each described by a CPT code. Identifying and developing appropriate payment policies that aim to achieve better care and improved health for Medicare beneficiaries is a priority for CMS. Consistent with that goal, we are interested in exploring new options for establishing PFS payment rates or adjustments for services that are furnished together. For purposes of this discussion, we will refer to the circumstances where a set of services is grouped together for purposes of ratesetting and payment as ''bundled payment.''

One of the mechanisms through which we support innovative payment and service delivery models, for Medicare and other beneficiaries, is through CMS' Center for Medicare and Medicaid Innovation (the Innovation Center). The Innovation Center is currently testing models in which payment for physicians' services is bundled on a per-beneficiary population basis, or is based on episodes of care that usually begin with a triggering

event and extend for a specified period of time thereafter. An example of a model in which payment is made on a per-beneficiary population basis is Comprehensive Primary Care Plus (CPC+), in which participating practices receive prospective per-beneficiary care management fees and Comprehensive Primary Care Payments for certain primary care services such as chronic care management and E/M services. An example of an episode payment model is the Oncology Care Model (OCM), in which participating physician practices receive a per-beneficiary Monthly Enhanced Oncology Services payment for care management and care coordination surrounding chemotherapy administration to cancer patients.

As noted in the CY 2020 PFS proposed rule, we are actively exploring the extent to which these basic principles of bundled payment, such as establishing per-beneficiary payments for multiple services or condition-specific episodes of care, can be applied within the statutory framework of the PFS. As such, we solicited comment on opportunities to expand the concept of bundling to recognize efficiencies among physicians' services paid under the PFS and better align Medicare payment policies with CMS' broader goal of achieving better care for patients, better health for our communities, and lower costs through improvement in our health care system. We believe that the statute, while requiring CMS to pay for physicians' services based on the relative resources involved in furnishing the service, allows considerable flexibility for developing payments under the PFS.

We received public comments on the solicitation on opportunities for bundled payments under the PFS.

Comment: We received many comments in response to this solicitation. Some commenters expressed general support for the concept of bundled payments while urging caution on the design and implementation, suggesting that specialty societies and the CPT Editorial Panel are positioned to identify opportunities for bundled payments. Other commenters stated that bundled payments are not within the statutory authority of the PFS and stated that CMS continue to use the Innovation Center to test these concepts.

Response: We thank the commenters for all the information submitted. We will review the many public comments we received on this topic and consider this issue further for potential future rulemaking.

P. Payment for Evaluation and Management (E/M) Visits

1. Background

a. E/M Visits Coding Structure

Physicians and other practitioners who are paid under the PFS bill for common office visits for evaluation and management (E/M) services under a relatively generic set of CPT codes (Level I HCPCS codes) that distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. These CPT codes are broadly referred to as E/M visit codes and have three key components within their code descriptors: history of present illness (History), physical examination (Exam), and medical decision-making (MDM).[83]

The CPT code descriptors recognize counseling, care coordination, and the nature of the presenting problem as additional service components, but these are contributory factors in determining which code to report.[84] Per the CPT code descriptors, counseling and/or care coordination are provided consistent with the nature of the problem and the patient's and/or family's needs. Counseling and care coordination are not required at every patient encounter and can be accounted for in separate coding.[85]

As finalized in the CY 2019 PFS final rule, the amount of time spent by the billing practitioner is not a determining factor in code level selection unless: (1) Counseling and care coordination dominate the visit, in which case time becomes the key factor in determining visit level; and/or (2) the service is a prolonged (or beginning in 2021, ''extended'') (83 FR 59630) E/M visit. Typical times for each level of E/M visit are included in each of the CPT code descriptors, are used for PFS rate setting purposes, and provide a reference point for the reporting of prolonged visits. Separate add-on codes describe, and can be reported for, visits that take prolonged (or beginning in 2021, ''extended'') (83 FR 59630) amounts of time.

There are 3 to 5 E/M visit code levels, depending upon site of service and the extent of the three components of history, exam, and MDM. For example, there are 3 to 4 levels of E/M visit codes in the inpatient hospital and nursing facility settings based on a relatively narrow range of complexity in those settings. In contrast, there are 5 levels of E/M visit codes in the office or other outpatient setting based on a broader range of complexity in those settings.

PFS payment rates for E/M visit codes generally increase with the level of visit billed, although in the CY 2019 PFS final rule (83 FR 59638), for reasons discussed below, we finalized the assignment of a single payment rate for levels 2 through 4 office/outpatient E/M visits beginning in CY 2021. As for all services under the PFS, the payment rates for E/M visits are based on the work (time and intensity), PE, and malpractice expense resources required to furnish the typical case of the service.

In total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services. Within the E/M services represented in these percentages, there is wide variation in the volume and level of E/M visits billed by different specialties. According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed services for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Generally, these practitioners include both primary care practitioners and certain specialists such as neurologists, endocrinologists and rheumatologists. Certain specialties, such as podiatry, tend to furnish lower level E/M visits more often than higher level E/M visits. Some specialties, such as dermatology and otolaryngology, tend to bill more E/M visits on the same day as they bill minor procedures.

b. E/M Documentation Guidelines

For CY 2019 and 2020, when coding and billing E/M visits to Medicare, practitioners may use one of two versions of the E/M Documentation Guidelines for a patient encounter, commonly referenced based on the year of their release: the ''1995'' or ''1997'' E/M Documentation Guidelines (hereafter, the 1995 and 1997 Guidelines).[86] These Guidelines specify the medical record information within each of the three key components (such as number of body systems reviewed) that serves as support

[83] 2019 CPT Codebook, Evaluation and Management, pp. 6–13.

[84] 2019 CPT Codebook, Evaluation and Management, pp. 6–13.

[85] 2019 CPT Codebook, Evaluation and Management, pp. 4–56.

[86] See *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf; https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf;* and the Evaluation and Management Services guide at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf.*

for billing a given level of E/M visit. The 1995 and 1997 Guidelines are very similar to the guidelines for E/M visits that currently reside within the AMA's CPT codebook for E/M visits. For example, the core structure of what comprises or defines the different levels of history, exam, and medical decision-making in the 1995 and 1997 Guidelines are the same as those in the CPT codebook. However, the 1995 and 1997 Guidelines include extensive examples of clinical work that comprise different levels of medical decision-making that do not appear in the AMA's CPT codebook. Also, the 1995 and 1997 Guidelines do not contain references to preventive care that appear in the AMA's CPT codebook. We provide an example of how the 1995 and 1997 Guidelines distinguish between level 2 and level 3 E/M visits in Table 32.

BILLING CODE 4120–01–P

TABLE 32: Key Component Documentation Requirements for Level 2 vs. 3 E/M Visit

Key Component*	Level 2 (1995)	Level 3 (1995)	Level 2 (1997)	Level 3 (1997)
History (History of Present Illness or HPI)	Review of Systems (ROS) n/a	Problem Pertinent ROS: inquires about the system directly related to the problem(s) identified in the HPI	No change from 1995	No change from 1995
Physical Examination (Exam)	A limited examination of the affected body area or organ system	A limited examination of the affected body area or organ system and other symptomatic or related organ system(s)	General multi-system exam: Performance and documentation of one to five elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of one to five elements	General multi-system exam: Performance and documentation of at least six elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of at least six elements
Medical Decision Making (MDM) Measured by:** 1. **Problem** – Number of diagnoses/treatment options 2. **Data -** Amount and/or complexity of data to be reviewed 3. **Risk-** Risk of complications and/or morbidity or mortality	Straightforward: 1. Minimal 2. Minimal or no data review 3.Minimal risk	Low complexity: 1. Limited. 2. Limited data review. 3. Low risk.	No change from 1995	

* For certain settings and patient types, each of these three key components must be met or exceeded (for example, new patients; initial hospital visits). For others, only two of the three key components must be met or exceeded (for example, established patients, subsequent hospital or other visits).

** Two of three met or exceeded.

BILLING CODE 4120–01–C

According to both Medicare claims processing manual instructions and CPT coding rules, when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time) the duration of the visit can be used as an alternative basis to select the appropriate E/M visit level (Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.C available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf; see* also 2019 CPT Codebook Evaluation and Management Services Guidelines, page 10). Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.B states, ''Instruct physicians to select the code for the service based upon the content of the service. The duration of the visit is an ancillary factor and does not control the level of the service to be billed unless more than 50 percent of the face-to-face time (for non-inpatient services) or more than 50 percent of the floor time (for inpatient services) is spent providing counseling or coordination of care as described in subsection C.'' Subsection C states that ''the physician may document time spent with the patient in conjunction with the medical decision-making involved and a description of the coordination of care or counseling provided. Documentation must be in sufficient detail to support the claim.''

The example included in subsection C further states, ''The code selection is based on the total time of the face-to-face encounter or floor time, not just the counseling time. The medical record must be documented in sufficient detail to justify the selection of the specific code if time is the basis for selection of the code.''

Both the 1995 and 1997 Guidelines address time, stating that, ''In the case where counseling and/or coordination of care dominates (more than 50 percent of) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), time is considered the key or controlling factor to qualify for a particular level of E/M services.'' The Guidelines go on to state that, ''If the physician elects to report the level of service based on counseling and/or coordination of care, the total length of time of the encounter (face-to-face or floor time, as appropriate) should be documented and the record should describe the counseling and/or activities to coordinate care.'' [87] Additional manual provisions regarding E/M visits are housed separately within Medicare's internet-Only Manuals, and are not contained within the 1995 or 1997 Guidelines.

In accordance with section 1862(a)(1)(A) of the Act, which requires services paid under Medicare Part B to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, medical necessity is a prerequisite to Medicare payment for E/M visits. Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.B states, ''Medical necessity of a service is the overarching criterion for payment in addition to the individual requirements of a CPT code. It would not be medically necessary or appropriate to bill a higher level of E/M service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which a specific level of service is billed. Documentation should support the level of service reported.''

c. Summary of Changes to Coding, Payment and Documentation of Office/Outpatient E/M Visits Finalized for CY 2021 in the CY 2019 PFS Final Rule

In the CY 2019 PFS final rule (83 FR 59452 through 60303), we finalized a number of coding, payment, and documentation changes under the PFS for office/outpatient E/M visits (CPT codes 99201–99215) to reduce administrative burden, improve payment accuracy, and update this code set to better reflect the current practice of medicine. In summary, we finalized the following policy changes for office/outpatient E/M visits under the PFS effective January 1, 2021:

- Reduction in the payment variation for office/outpatient E/M visit levels by paying a single rate (also referred to as a blended rate) for office/outpatient E/M visit levels 2 through 4 (one rate for established patients and another rate for new patients), while maintaining the payment rate for office/outpatient E/M visit level 5 in order to better account for the care and needs of complex patients. Practitioners will still report the appropriate code for the level of service they furnished, since we did not replace these CPT codes with HCPCS G codes and will continue to use typical times associated with each individual CPT code when time is used to document the office/outpatient E/M visit.
- Permitting practitioners to choose to document office/outpatient E/M level 2 through 5 visits using MDM or time, or the current framework based on the 1995 or 1997 Guidelines.
- As a corollary to the uniform payment rate for level 2–4 E/M visits, when using MDM or the current framework to document the office/outpatient E/M visit, a minimum supporting documentation standard associated with level 2 office/outpatient E/M visits will apply. For these cases, Medicare will require information to support a level 2 office/outpatient E/M visit code for history, exam, and/or MDM.
- When time is used to document, practitioners will document the medical necessity of the office/outpatient E/M visit and that the billing practitioner personally spent the required amount of time face-to-face with the beneficiary. The required face-to-face time will be the typical time for the reported code, except for extended or prolonged visits where extended or prolonged times will apply.
- Implementation of HCPCS add-on G codes that describe the additional resources inherent in visits for primary care and particular kinds of non-procedural specialized medical care (HCPCS codes GPC1X and GCG0X, respectively). These codes were finalized in order to reflect the differential resource costs associated with performing certain types of office/outpatient E/M visits. These codes will only be reportable with office/outpatient E/M level 2 through 4 visits.
- Adoption of a new ''extended visit'' add-on G code (HCPCS code GPRO1) for use only with office/outpatient E/M level 2 through 4 visits, to account for the additional resources required when practitioners need to spend extended time with the patient for these visits. The existing prolonged E/M codes can continue to be used with levels 1 and 5 office/outpatient E/M visits.

We stated that we believed these policies would allow practitioners greater flexibility to exercise clinical judgment in documentation so they can focus on what is clinically relevant and medically necessary for the beneficiary. We believed these policies will reduce a substantial amount of administrative burden (83 FR 60068 through 60070) and result in limited specialty-level redistributive impacts (83 FR 60060). We stated our intent to continue engaging in further discussions with the public over the next several years to potentially further refine our policies for 2021. We finalized the coding, payment, and documentation changes to reduce administrative burden, improve payment accuracy, and update the code set to better reflect the current practice of medicine.

2. Continued Stakeholder Feedback

In January and February 2019, we hosted a series of structured listening sessions on the forthcoming changes that CMS finalized for office/outpatient E/M visit coding, documentation and payment for CY 2021. These sessions provided an opportunity for CMS to gain further input and information from the wide range of affected stakeholders on these important policy changes. Our goal was to continue to listen and consider perspectives from individual practicing clinicians, specialty associations, beneficiaries and their advocates, and other interested stakeholders to prepare for implementation of the office/outpatient E/M visit policies that we finalized for CY 2021.

In these listening sessions, although stakeholders supported our intention to reduce burdensome, clinically outdated documentation requirements, they noted that in response to the office/outpatient E/M visit policies CMS finalized for CY 2021, the AMA/CPT established the Joint AMA CPT Workgroup on E/M to develop an alternative solution. This workgroup developed an alternative approach, similar to the one we finalized, for office/outpatient E/M coding and documentation. That approach was approved by the CPT Editorial Panel in February 2019, with an effective date of January 1, 2021 and is available on the

[87] Page 16 of the 1995 E/M guidelines and page 48 of the 1997 guidelines.

AMA's website at *https://www.ama-assn.org/cpt-evaluation-and-management*. Given the CPT coding changes that will take effect in 2021, the AMA RUC also conducted a resurvey and revaluation of the office/outpatient E/M visit codes, and provided us with its recommendations.

Effective January 1, 2021, the CPT Editorial Panel adopted revisions to the office/outpatient E/M code descriptors, and substantially revised both the CPT prefatory language and the CPT interpretive guidelines that instruct practitioners on how to bill these codes. The AMA has approved an accompanying set of interpretive guidelines governing and updating what determines different levels of MDM for office/outpatient E/M visits. Some of the changes made by the CPT Editorial Panel parallel our finalized policies for CY 2021, such as the choice of time or MDM in determination of code level. Other aspects differ, such as the number of code levels retained, presumably for purposes of differential payment; the times, and inclusion of all time spent on the day of the visit; and elimination of options such as the use of history and exam or time in combination with MDM, to select code level.

Many stakeholders have continued to express objections to our assignment of a single payment rate to level 2–4 office/outpatient E/M visits stating that this inappropriately incentivizes multiple, shorter visits and seeing less complex patients. Many stakeholders also stated that the purpose and use of the HCPCS add-on G codes that we established for primary care and non-procedural specialized medical care remain ambiguous, expressed concern that the codes are potentially contrary to current law prohibiting specialty-specific payment, and asserted that Medicare's coding approach is unlikely to be adopted by other payers.

In meetings with stakeholders since we issued the CY 2019 PFS final rule, some stakeholders suggested that only time should be used to select the service level because time is easy to audit, simple to document, and better accounts for patient complexity, in comparison to the CPT Editorial Panel revised MDM interpretive guidance. These stakeholders stated that the implementation of the CPT Editorial Panel revised MDM interpretive guidance will result in the likely increase in the selection of levels 4 and 5, relative to current typical coding patterns. They suggested that to more accurately distinguish varying levels of patient complexity, either the visit levels should be recalibrated so that levels 4 and 5 no longer represent the most often billed visit, or a sixth level should be added. In these meetings, some stakeholders also stated that the office/outpatient E/M codes fail to capture the full range of services provided by certain specialties, particularly primary care and other specialties that rely heavily on office/outpatient E/M services rather than procedures, systematically undervaluing primary care visits and visits furnished in the context of non-procedural specialty care, thereby creating payment disparities that have contributed to workforce shortages and beneficiary access challenges across a range of specialties. They reiterated that office/outpatient E/M visit codes have not been extensively examined since the creation of the PFS and recommended that CMS conduct an extensive research effort to revise and revalue office/outpatient E/M services through a major research initiative akin to that undertaken when the PFS was first established.

The AMA believes its approach will accomplish greater burden reduction, is more clinically intuitive and reflects the current practice of medicine, and is more likely to be adopted by all payers than the policies CMS finalized for CY 2021. The AMA has posted an estimate of the burden reduction associated with the policies approved at CPT on the AMA's website at *https://www.ama-assn.org/cpt-evaluation-and-management.*

3. CY 2021 PFS Final Policies for Office/Outpatient Visits

a. Overview

In the CY 2020 PFS proposed rule, we discussed our proposal to adopt the CPT coding for office/outpatient E/M visits effective January 1, 2021, noting that the CPT coding changes will necessitate changes to CMS' policies for CY 2021, due to forthcoming changes in code descriptors. In addition, we addressed revaluation of the codes, proposing new values for the codes as revised by CPT, that would also take effect on January 1, 2021. We proposed to assign separate payment rather than a blended rate, to each of the office/outpatient E/M visit codes (except CPT code 99201, which CPT is deleting) and the new prolonged visit add-on CPT code (CPT code 99XXX). We proposed to delete the HCPCS add-on code we finalized last year for CY 2021 for extended visits (GPRO1), and to no longer pay separately for CPT codes 99358–9 (prolonged E/M visit without direct patient contact) in association with office/outpatient E/M visits. We proposed to simplify, consolidate and revalue the HCPCS add-on codes we finalized last year for CY 2021 for primary care (GPC1X) and non-procedural specialized medical care (GCG0X), and to allow the consolidated single code to be reported with all office/outpatient E/M visit levels (not just levels 2 through 4). All of these changes would be effective January 1, 2021. We noted that our proposed policies would further our ongoing effort to reduce administrative burden, improve payment accuracy, and update the office/outpatient EM visit code set to better reflect the current practice of medicine.

We received many thousands of comments in response to these proposals. The following is a summary of the comments and our response.

b. Public Comments and Responses

(1) Office/Outpatient E/M Visit Coding and Documentation

For CY 2021, for office/outpatient E/M visits (CPT codes 99201–99215), we proposed generally to adopt the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA/CPT (*see https://www.ama-assn.org/cpt-evaluation-and-management*) because we believed it would accomplish greater burden reduction than the policies we finalized for CY 2021 and would be more intuitive and consistent with the current practice of medicine. We noted that this includes deletion of CPT code 99201 (Level 1 office/outpatient visit, new patient), which the CPT Editorial Panel decided to eliminate as CPT codes 99201 and 99202 are both straightforward MDM and only differentiated by history and exam elements.

Under this new framework, history and exam would no longer be used to select the level of code for office/outpatient E/M visits. Instead, an office/outpatient E/M visit would include a medically appropriate history and exam, when performed. The clinically outdated system for number of body systems/areas reviewed and examined under history and exam would no longer apply, and these components would only be performed when, and to the extent, medically necessary and clinically appropriate. Level 1 visits would only describe or include visits performed by clinical staff for established patients, and the concept of medical decision making would not apply to CPT code 99211.

For levels 2 through 5 office/outpatient E/M visits, the code level reported would be decided based on either the level of MDM (as redefined in

the new AMA/CPT guidance framework) or the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time). Because we would no longer assign a blended payment rate (discussed below), we would no longer adopt the minimum supporting documentation associated with level 2 office/outpatient E/M visits, which we had finalized in the CY 2019 PFS final rule (83 FR 59634) as a corollary to the uniform payment rate for level 2–4 office/outpatient E/M visits when using MDM or the current framework to document the office/outpatient E/M visit. We would adopt the new time ranges within the CPT codes as revised by the CPT Editorial Panel.

Comment: Commenters were generally supportive of our proposals to eliminate the blended payment rate and instead adopt the revised CPT coding and levels for separate payment, including the choice of selecting visit level on the basis of time or MDM. The commenters agreed that these proposals would reduce administrative burden, improve payment accuracy, and better reflect the current practice of medicine. However, a number of commenters disagreed with the new MDM guidelines and believe they need further refinement before implementation. A few commenters believed the revised guidelines represent a critical first step and supported them as such, but were concerned that they fail to capture all the inputs for the visit (especially physical exam) and the complexity (intensity) of the patient with multiple issues; may continue to result in undesired cutting and pasting in the medical record; and fail to properly differentiate levels (particularly level 2 versus 3, and level 3 versus 4). These commenters were concerned that the revised MDM criteria may not prevent upcoding or prevent the accumulation of meaningless or repetitive information in the medical record just for billing purposes, and suggested that CMS work with the Office of the National Coordinator for Health Information Technology (ONC) on ways to accomplish ''behind-the-scenes'' documentation in support of the data review associated with MDM.

One commenter supported using time as the basis for choosing the E/M code, but expressed concern about using MDM as one of the primary factors to determine E/M levels. This commenter viewed time as the most important factor, and was concerned about MDM levels failing to account for the complexity of neurologic patients and difficulty attaining the highest level of E/M code using MDM alone. This commenter suggested there will be an increase in reporting of levels 4 and 5 office/outpatient E/M visits under the new construct that may necessitate recalibrating the visit levels.

A few commenters suggested that when time is used to determine visit level selection that it should be based on time spent during the 24-hour period that includes the face-to-face visit, in recognition of those practitioners who see patients during evening clinic hours. Similarly, when MDM is used to determine visit level, some commenters expressed concern that MDM cannot be concluded until practitioners receive test results, which may not occur until after the date of the encounter.

Response: We agree that the MDM guidelines as revised by the AMA/CPT represent a good first step in reducing burden and updating the different levels of MDM for the current practice of medicine, as well as the coming 2021 definitional changes in this code set. We agree with the majority of commenters that time and MDM are each important measures of office/outpatient E/M visit complexity that practitioners should have the option to use to select visit level, and that history and physical exam only need to be performed and documented as medically appropriate. Therefore, we are finalizing our proposal to adopt the MDM guidelines as revised by CPT and allow the use of time or MDM to select office/outpatient E/M visit level beginning January 1, 2021. We share some of the commenters' concerns about potential resulting shifts in visit levels billed and among specialties, and intend to monitor the claims data to assess any resulting changes. We will continue to consider whether future refinements to the office/outpatient E/M visit code set, its valuation, and supporting documentation may be needed. We refer readers to our comment/response below on the prolonged service codes regarding the applicable time period for the primary office/outpatient E/M visit code and prolonged service code(s). Finally, the AMA/CPT has indicated it will undertake educational efforts on its new guidelines that we expect might clarify outstanding questions such as the application of test results received on subsequent dates when MDM is used to select visit level.

Comment: A few commenters stated that CPT's new documentation guidelines for the revised office/outpatient E/M code set that would permit code selection based on either MDM or time did not accurately represent MDM activities for urgent care practitioners who report office/outpatient E/Ms in the urgent care setting. These commenters were concerned that the revised MDM criteria fail to account for the complexity of the patient with multiple issues and would result in inaccurate visit level selection, and recommended that CMS allow urgent care practitioners to use either the 1995 and 1997 Guidelines or CPT's new documentation guidelines for the revised office/outpatient E/M code set and allow data to be gathered to monitor it over time.

Response: We appreciate these concerns, but we believe that allowing practitioners to use either the 1995 and 1997 Guidelines or CPT's new documentation guidelines for the revised office/outpatient E/M code set would create further burden. In the CY 2019 PFS proposed rule, we proposed to allow practitioners a choice between the 1995 and 1997 Guidelines, MDM alone, or time alone to document office/outpatient E/M services. In response to this proposal, commenters stated that ''such a policy would introduce too much variation in medical record format and content, or too many potential frameworks against which an auditor might review a claim'' (83 FR 59633). Because we believe that CPT's new documentation guidelines for the revised office/outpatient E/M code set accomplishes greater burden reduction than the policies we finalized for CY 2021 in the CY 2019 PFS final rule, we are finalizing our proposal to adopt the MDM guidelines as revised by CPT and allow the use of time or MDM to select office/outpatient E/M visit level. We share some of the commenters' concerns about potential resulting shifts in visit levels billed and among specialties, and intend to monitor the claims data to assess any resulting changes. We will continue to consider whether future refinements to the office/outpatient E/M visit code set, its valuation, and supporting documentation may be needed.

We interpreted the revised CPT prefatory language and reporting instructions to mean that there would be a single add-on CPT code for prolonged office/outpatient E/M visits (CPT code 99XXX *(Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)*) that would only be reported when time is used for code level

selection and the time for a level 5 office/outpatient visit (the floor of the level 5 time range) is exceeded by 15 minutes or more on the date of service. We demonstrated how prolonged office/outpatient E/M visit time would be reported:

TABLE 33: Proposed Total Practitioner Times for Office/Outpatient E/M Visits When Time Is Used to Select Visit Level

Established Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)	CPT code
40–54 minutes	99215
55-69 minutes	99215x1 and 99XXXx1
70-84 minutes	99215x1 and 99XXXx2
85 or more minutes	99215x1 and 99XXXx3 or more for each additional 15 minutes
New Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)	**CPT code**
60-74 minutes	99205
75-89 minutes	99205x1 and 99XXXx1
90-104 minutes	99205x1 and 99XXXx2
105 or more minutes	99205x1 and 99XXXx3 or more for each additional 15 minutes

Comment: Commenters supported the proposal to adopt CPT code 99XXX to report all prolonged time spent on the day of the visit. Several commenters sought to clarify that day or date of visit means the 24-hour period for the date of service of the reported office/outpatient E/M visit code.

Response: We are finalizing our proposal to adopt CPT code 99XXX to report all prolonged time spent on the date of the primary office/outpatient E/M visit code, which is the 24-hour period for the date of service reported for the primary office/outpatient E/M visit code.

We also proposed to adopt our interpretation of the revised CPT prefatory language and reporting instructions, that CPT codes 99358–9 (*Prolonged E/M without Direct Patient Contact*) would no longer be reportable in association or ''conjunction'' with office/outpatient E/M visits. In other words, when using time to select office/outpatient E/M visit level, any additional time spent by the reporting practitioner on a prior or subsequent date of service (such as reviewing medical records or test results) could not count toward the required times for reporting CPT codes 99202–99215 or 99XXX, or be reportable using CPT codes 99358–9. This interpretation would be consistent with the way the office/outpatient E/M visit codes were resurveyed, where the AMA/RUC instructed practitioners to consider all time spent 3 days prior to, or 7 days after, the office/outpatient E/M visit (*see* below for a discussion of revaluation proposals). Moreover we noted that CPT codes 99358 and 99359 describe time spent beyond the ''usual'' time (CPT prefatory language), and it was not clear what would comprise ''usual'' time given the new time ranges for the office/outpatient E/M visit codes and new CPT code 99XXX (prolonged office/outpatient E/M visit).

New CPT prefatory language specifies, ''For prolonged services on a date other than the date of a face-to-face encounter, including office or other outpatient services (99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215), see 99358, 99359 . . . Do not report 99XXX in conjunction with . . . 99358, 99359''. We did not believe CPT code 99211 should be included in this list of base codes since it will only include clinical staff time. Also, given that CPT codes 99358, 99359 can currently be used to report practitioner time spent on any date (the date of the visit or any other day), and it was not clear whether CPT changed this rule, the CPT reporting instruction ''see 99358, 99359'' seemed circular. The new prefatory language seemed unclear regarding whether CPT codes 99358, 99359 could be reported instead of, or in addition to, CPT code 99XXX, and whether the prolonged time would have to be spent on the visit date, within 3 days prior or 7 days after the visit date, or outside of this new 10-day window relevant for the base code.

We solicited public input on the proposal and whether it would be appropriate to interpret the CPT reporting instructions for CPT codes 99358–99359 as proposed, as well as how this interpretation may impact valuation. We stated our belief that CPT codes 99358 and 99359 may need to be redefined, resurveyed and revalued. After internal review, we believed that when time is used to select visit level, having one add-on code (CPT code 99XXX) instead of multiple add-on codes for additional time may be administratively simpler and most consistent with our goal of documentation burden reduction.

HCPCS code GPRO1 (*extended office/outpatient E/M time*) would no longer be needed because the time described by this code would instead be described by a level 3, 4 or 5 office/outpatient E/M visit base code and, if applicable, the single new add-on CPT code for prolonged office/outpatient E/M visits (CPT code 99XXX). Therefore, we proposed to delete HCPCS code GPRO1 for CY 2021. We proposed to adopt the AMA/CPT prefatory language that lists qualifying activities that could be included when time is used to select the visit level. Alternatively, if MDM is used to choose the visit level, time would not be relevant to code selection.

Comment: Some commenters sought clarification on apparent overlap between CPT codes 99358–99359 and 99XXX, and recommended that CPT review this. Some commenters specified that there should continue to be a way to code and bill separately for prolonged time spent on a day other than the visit, such as for medical record review in advance of a new patient visit. In their public comment, the AMA/RUC noted that CPT codes 99358–99359 are not frequently reported, and recommended that the CPT/RUC Workgroup on E/M should review the issues raised in our

proposed rule regarding CPT codes 99358–99359 and ensure that the codes and guidelines are clarified, as needed, prior to any future RUC survey.

Response: Since Medicare began separately paying for CPT codes 99358–99359 in 2017 under the PFS, their PFS utilization has increased more than ten-fold from approximately 10,000 claim lines in 2016 to approximately 126,000 claim lines in 2018. While this remains a small percentage of E/M visit claims, utilization may further increase once all office/outpatient E/M visits can be reported on the basis of time alone and new activities such as documenting clinical information are explicitly counted as qualifying time. We continue to believe that the new CPT prefatory language on these codes is difficult to follow and interpret. For example, it states, ''for prolonged time without direct patient contact on the date of office or other outpatient services, use 99xxx. Codes 99358, 99359 may also be used for prolonged services on a date other than the date of a face-to-face encounter.'' But for CPT code 99xxx it states not to report 99xxx in conjunction with 99358, 99359 which could mean not to report 99358–99359 if 99xxx is reported, even on a separate day. Additionally, CPT would allow reporting at the midpoint of time for CPT codes 99358–99359 but not 99XXX, and these codes have discrepant time increments (one hour for CPT codes 99358–9 reportable after the midpoint, and 15 minutes for CPT code 99XXX not reportable after the midpoint).

Under the new CPT framework allowing the use of time to select visit level and the new list of qualifying activities, there is a new Medicare program vulnerability and potential increased beneficiary cost sharing associated with the inability to assess what visit(s) prolonged service codes reported on a date other than the visit are associated with and, accordingly, to assess whether the prolonged time was reasonable and necessary. If more than one visit was furnished (for example, if a beneficiary has an inpatient visit or another outpatient visit by the same practitioner within a wide time range of a given office/outpatient visit), it would not be clear which visit the prolonged time reported under CPT codes 99358–99359 is associated with for evaluating medical necessity and increments of time in relation to the base/companion code.

We continue to believe it would be administratively simpler and improve payment accuracy and program integrity to have only a single add-on code specific to prolonged office/outpatient E/M visits that is clearly linked to the companion E/M office/outpatient visit code. We believe that under the new coding framework, CPT codes 99358–99359 are potentially misvalued, need to be revised for clarity and present new program integrity challenges. Therefore, we are finalizing our proposal that CPT codes 99358–99359 will not be payable in association with office/outpatient E/M visits beginning in CY 2021. We will consider future changes made to these codes by the CPT Editorial Panel or the RUC for possible future rulemaking. We note that a number of other codes such as CCM, TCM, and other care management codes may be used to report time spent outside the direct patient contact on dates other than the office/outpatient visit, if the reporting requirements for those services are met. While these care management codes are not identical to the prolonged visit codes, they can be used to report a number of similar activities.

Comment: Commenters supported the proposal to delete HCPCS code GPRO1 for CY 2021 and to adopt the AMA/CPT prefatory language that lists qualifying activities that could be included when time is used to select the visit level. Alternatively, if MDM is used to choose the visit level, time would not be relevant to code selection.

Response: We are finalizing as proposed that GPRO1 will be deleted. Also, the new CPT prefatory language listing qualifying activities that can be included when time is used to select the visit level will apply for purposes of PFS payment. Alternatively, if MDM is used to choose the visit level, time will not be relevant to code selection.

Comment: Several commenters expressed concern regarding the use of physician and nonphysician practitioner (NPP) time and documentation as it pertains to a split/shared encounter when a beneficiary sees both the physician and NPP at one visit. One commenter questioned whether, when considering the use of an add-on code for time, the documented time would be limited to only one practitioner's time spent providing the service, or the time could include a combination of more than one physician and/or clinician providing the service. Another commenter stated that the CPT guidelines are inconsistent with the Medicare guidelines for split/shared E/M services. The commenter stated that per CMS guidelines, ''split/shared'' office visit E/M services only apply to established patients, while the new CPT introductory guidelines for the new patient office visit codes 99202–99205, specifically describe ''incident to'' work and time of both the physician and QHP for selecting a level of code. The commenter requested CMS clarify its incident-to policy rules relative to the revised CPT guidelines for new patient office visit codes.

One commenter requested that CMS consider the impact to the split/shared services guidelines as it incorporates documentation from a physician and a NPP. The commenter stated that policies set forth by the Medicare Administrative Contractors (MACs) require specific documentation of the second practitioner's participation in the delivery of the service in the medical record to support medical necessity for their participation and inquired how the impact of time and medical decision making changes impact these other regulations. The commenter detailed their concerns with the current proposal as it relates to split/shared services and asked whether CMS would clarify or redefine the documentation requirements for physician assistants (PAs) advanced practice registered nurses (APRNs), or physicians for these types of services. The commenter further requested clarification on how best to select appropriate E/M levels when practitioners use time to support their levels of service and two practitioner types are involved in furnishing care to the same patient on the same day. The commenter also asked whether CMS is considering a change in payment for PAs and APRNs, if so, whether it would be at the same rate for physician, and if not, how these new proposed documentation changes define the billing practitioner.

Response: We did not make any proposals specific to split/shared services in the CY 2020 PFS proposed rule. We thank the public commenters for raising these issues. We will review and take into account the public comments received on this topic and will consider the issues raised in the comments for possible future rulemaking.

Comment: Several commenters expressed concern that practitioners who report E/M services in multiple settings (for example, hospital inpatient services, emergency department services) would be required to document and create billing protocols under one set of rules for office/outpatient E/M visits and another set of rules for other E/M settings. These commenters recommended that CMS should apply CPT's new documentation guidelines for the revised office/outpatient E/M code set to all E/M services in all settings.

Response: Although we did not make any proposals in this regard for CYs 2020 or 2021, we appreciate the

information submitted. We will review and take into account the public comments received on this topic and will consider the issues raised in the comments for possible future rulemaking.

(2) Office/Outpatient E/M Visit Revaluation (CPT Codes 99201 Through 99215)

We received valuation recommendations from the AMA RUC for the revised office/outpatient E/M visit codes (CPT codes 99201 through 99215) following completion of its survey and revaluation process for these codes. Although these codes do not take effect until CY 2021, we believed that it was appropriate to follow our usual process of addressing the valuation of the revised office/outpatient E/M visit codes through rulemaking after we receive the RUC recommendations. Additionally, establishing values for the new codes through rulemaking this year will allow more time for clinicians to make any necessary process and systems adjustments before they begin using the codes. In recent years, we have considered how best to update and revalue the office/outpatient E/M visit codes as they represent a significant proportion of PFS expenditures.

MedPAC has had longstanding concerns that office/outpatient E/M services are undervalued in the PFS, and in its March 2019 Report to Congress, further asserted that the office/outpatient E/M code set has become passively devalued as values of these codes have remained unchanged, while the coding and valuation for other types of services under the fee schedule have been updated to reflect changes in medical practice (*see* pages 120 through 121 at *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch4_sec.pdf?sfvrsn=0*).

In April 2019, the RUC provided us the results of its review, and recommendations for work RVUs, PE inputs and physician time (number of minutes) for the revised office/outpatient E/M visit code set. Please note that these changes in coding and values are for the revised office/outpatient E/M visit code set and a new 15-minute prolonged services code. That code set is effective beginning in CY 2021, and the values would go into effect with those codes as of January 1, 2021.

We proposed to adopt the RUC-recommended work RVUs for all of the office/outpatient E/M visit codes and the new prolonged services add-on code. Specifically, we proposed a work RVU of 0.93 for CPT code 99202 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 15–29 minutes of total time is spent on the date of the encounter*), a work RVU of 1.6 for CPT code 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 30–44 minutes of total time is spent on the date of the encounter*), a work RVU of 2.6 for CPT code 99204 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 45–59 minutes of total time is spent on the date of the encounter*), a work RVU of 3.5 for CPT code 99205 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60–74 minutes of total time is spent on the date of the encounter. (For services 75 minutes or longer, see Prolonged Services 99XXX)*), a work RVU of 0.18 for CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal*)), a work RVU of 0.7 for CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter*), a work RVU of 1.3 for CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter),* a work RVU of 1.92 for CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter*), a work RVU of 2.8 for CPT code 99215 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 40–54 minutes of total time is spent on the date of the encounter. (For services 55 minutes or longer, see Prolonged Services 99XXX)*) and a work RVU of 0.61 for CPT code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)*).

Regarding the RUC recommendations for PE inputs for these codes, we proposed to remove equipment item ED021 (*computer, desktop, with monitor*), as we do not believe that this item would be allocated to the use of an individual patient for an individual service; rather, we believe this item is better characterized as part of indirect costs similar to office rent or administrative expenses as per our standard process for refining PE for this and other services.

The information we reviewed on the RUC valuation exercise was based on an extensive survey the RUC conducted of more than 50 specialty societies. For purposes of valuation, survey respondents were asked to consider the total time spent on the day of the visit, as well as any pre- and post-service time occurring within a timeframe of 3 days prior to the visit and 7 days after, respectively. This is different from the way codes are usually surveyed by the RUC for purposes of valuation, where pre-, intra-, and post-service time were surveyed, but not within a specific timeframe. The RUC then separately averaged the survey results for pre-service, day of service, and post-service times, and the survey results for total time, with the result that, for some of the codes, the sum of the times associated with the three service periods does not match the RUC-recommended total time. The RUC's approach sometimes resulted in two conflicting sets of times: The component times as surveyed and the total time as surveyed. Although we proposed to adopt the RUC-recommended times as explained below, we solicited comment on how

CMS should address the discrepancies in times, which have implications both for valuation of individual codes and for PFS ratesetting in general, as the intra-service times and total times are used as references for valuing many other services under the PFS and that the programming used for PFS ratesetting requires that the component times sum to the total time. Specifically, we solicited comment on which times should CMS use, and how we should resolve differences between the component and total times when they conflict. Table 34 illustrates the surveyed times for each service period and the surveyed total time. It also shows the actual total time if summed from the component times.

TABLE 34: RUC-Recommended Pre-, Intra-, Post-Service Times, RUC-Recommended Total Times for CPT codes 99202-99215 and Actual Total Time

HCPCS	Pre-Service Time	Intra-Service Time	Immediate Post-Service Time	Actual Total Time	RUC-recommended Total Time
99202	2	15	3	20	22
99203	5	25	5	35	40
99204	10	40	10	60	60
99205	14	59	15	88	85
99211		5	2	7	7
99212	2	11	3	16	18
99213	5	20	5	30	30
99214	7	30	10	47	49
99215	10	45	15	70	70

Table 35 summarizes the current office/outpatient E/M visit code set, and the new prolonged services code physician work RVUs and total time compared to what CMS finalized in CY 2019 for CY 2021, and the RUC-recommended work RVU and total time.

TABLE 35: Side by Side Comparison of Work RVUs and Physician Time for the Office/Outpatient E/M Services Code Set, and the New Prolonged Services Code (Current Versus Revised)

HCPCS Code	Current Total Time (mins)	Current Work RVU	CY 2021 Total Time (mins)	CY 2021 Work RVU	RUC rec Total Time (mins)	RUC rec Work RVU
99201	17	0.48	17	0.48	N/A	N/A
99202	22	0.93	22	1.76	22	0.93
99203	29	1.42	29	1.76	40	1.6
99204	45	2.43	45	1.76	60	2.6
99205	67	3.17	67	3.17	85	3.5
99211	7	0.18	7	0.18	7	0.18
99212	16	0.48	16	1.18	18	0.7
99213	23	0.97	23	1.18	30	1.3
99214	40	1.5	40	1.18	49	1.92
99215	55	2.11	55	2.11	70	2.8
99XXX	N/A	N/A	N/A	N/A	15	0.61

The RUC recommendations reflect a rigorous and robust survey approach, including surveying over 50 specialty societies, demonstrate that office/outpatient E/M visits are generally more complex, for most clinicians. In the CY 2019 PFS final rule, we finalized for CY 2021 a significant reduction in the payment variation in office/outpatient E/M visit levels by paying a single blended rate for E/M office/outpatient visit levels 2 through 4 (one for established and another for new patients). We also maintained the separate payment rates for E/M office/outpatient level 5 visits in order to better account for the care and needs of particularly complex patients. We believed that the single blended payment rate for E/M office/outpatient visit levels 2–4 better accounted for the resources associated with the typical visit. After reviewing the RUC recommendations, in conjunction with the revised code descriptors and documentation guidelines for CPT codes 99202 through 99215, we believe codes and recommended values would more accurately account for the time and intensity of office/outpatient E/M visits than either the current codes and values or the values we finalized in the CY 2019 PFS final rule for CY 2021. Therefore, we proposed to establish separate values for Levels 2–4 office/outpatient E/M visits for both new and

established patients rather than continue with the blended rate. We proposed to accept the RUC-recommended work and time values for the revised office/outpatient E/M visit codes without refinement for CY 2021. With regard to the RUC's recommendations for PE inputs, we proposed to remove equipment item ED021 (computer, desktop, with monitor), as this item is included in the overhead costs. Note that these changes to codes and values would go into effect January 1, 2021.

We received public comments on the proposed Office/Outpatient E/M Visit Revaluation provisions. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported revision of CMS' finalized policies, including blended payment rate for levels 2–4 and CMS' proposed adoption of the RUC recommended values for CPT codes 99202–99215, and 99xxx, deleting CPT code 99201, and maintaining separate payment for the remaining codes.

A few commenters expressed concern with the RUC-recommended values, stating that the standard for compelling evidence had not been met, that the survey instrument was flawed, and that the survey respondents may not have understood the survey method or the new coding guidance itself. These commenters urged CMS to delay implementation of the RUC-recommended times and RVUs until the public is more familiar with the new coding system, at which time the codes could be resurveyed by the RUC.

Response: With regard to the concerns raised regarding the RUC survey process and revaluation effort, we recognize that valuation of codes is an iterative process and that estimates may need to be updated. Due to the robust nature of the survey and the consensus of the RUC participants, we believe that the combination of adopting the CPT's revised code set and accepting the RUC-recommended values will represent a significant improvement in the description and payment of office and outpatient E/M visits over the current coding and values. We believe the RUC process and resultant recommendations provide a sufficient basis on which to set values for CY 2021; and that this is especially so given that there is sufficient time to consider any additional information developed before the new code set and values take effect. We note that the updated values are not effective until CY 2021, and will consider additional information pertaining to valuation of these services if submitted prior to the February 10, 2020 deadline for submission of RUC and/or stakeholder valuation recommendations to be considered for CY 2021 rulemaking.

Comment: Most commenters did not support the classification of equipment item ED021 (*computer, desktop, with monitor*) as an indirect PE, stating that the computer was an important part of furnishing the service, used for documentation or to view test results, and was not available for other uses while a visit was being furnished. A few commenters suggested that the office/outpatient E/M visit codes should include as direct PE 2 minutes for identifying and obtaining imaging, lab, or other test results.

Response: We continue to believe that ED021 is best characterized as an indirect PE. Although desktop computers may be used perform not only administrative tasks, but also a number of clinical tasks such as recording information about the patient obtained during evaluation or accessing the patient's history during the visit, we continue to believe that the majority of the functionality of a desktop computer is not individually allocable to a particular patient for a particular service. We also note that there are a number of services similar to an office visit, such as CPT code 99483 (*Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (e.g., basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (e.g., functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (e.g., home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neurocognitive symptoms, functional limitations, and referral to community resources as needed (e.g., rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver*) and CPT code 99490 (*Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored*) that do not include equipment item ED021 as a direct PE input despite specifically requiring information be entered into an EHR or other tasks that would typically be completed using a desktop computer. Beyond the classification of the desktop computer as an indirect PE, we believe that the PE inputs as recommended to CMS by the RUC are accurate, and as such, we do not agree that additional time is needed for identifying and obtaining imaging, lab, or other test results.

Comment: Many commenters recommended that, for purposes of ratesetting and the CMS time file, CMS should consider total time to be the median total time as recommended by the RUC.

Response: We thank the commenters for their suggestions. Currently, for ratesetting and the CMS time file, the total time for the office/outpatient E/M code set is the sum of pre-, intra-, and post-service times. If we were to consider the median total time as recommended by commenters and the RUC, then the pre-, intra-, and post-services times would no longer, in some instances, sum to the total. As we noted in the proposed rule, this has implications both for valuation of individual codes and for PFS ratesetting in general, as the intra-service times and total times are used as references for valuing many other services under the PFS and that the programming used for PFS ratesetting requires that the component times sum to the total time. We will continue to consider this issue in future rulemaking.

Comment: Many commenters expressed concerns about the redistributive impact of revaluing of the office/outpatient E/M visit code set, particularly for practitioners who do not routinely bill office/outpatient E/M visits. Commenters suggested a number of strategies CMS could use to mitigate

the negative redistributive impact, such as phasing the changes in over 4 or 5 years, capping increases or decreases, conducting claims-based analysis, and working with Congress to ensure that these changes would not negatively impact the CY 2021 conversion factor.

Response: As these office/outpatient E/M visit codes make up around 20 percent of total PFS expenditures, we understand commenters' concerns with the magnitude of the redistributive adjustment necessary to budget neutralize the increased values. Given that these revised codes and values do not take effect until CY 2021, and we do not know the magnitude of redistribution resulting from other policies we may adopt through rulemaking before then, we believe it would be premature to finalize a strategy in this final rule as these values would not be effective until CY 2021. However, we intend to consider these concerns and address them in future rulemaking.

Based on our review of public comments, we are finalizing valuation for CPT codes 99202 through 99215, as proposed for implementation beginning in CY 2021.

(3) Simplification, Consolidation and Revaluation of HCPCS Codes GCG0X and GPC1X

Although we believe that the RUC-recommended values for the revised office/outpatient E/M visit codes will more accurately reflect the resources involved in furnishing a typical office/outpatient E/M visit, we believe that the revalued office/outpatient E/M visit code set itself still does not appropriately reflect differences in resource costs between certain types of office/outpatient E/M visits. In the CY 2019 PFS proposed rule, we articulated that, based on stakeholder comments, clinical examples, and our review of the literature on office/outpatient E/M services, there are three types of office/outpatient E/M visits that differ from the typical office/outpatient E/M visit and are not appropriately reflected in the current office/outpatient E/M visit code set and valuation. These three types of office/outpatient E/M visits can be distinguished by the mode of care provided and, as a result, have different resource costs. The three types of office/outpatient E/M visits that differ from the typical office/outpatient E/M service are: (1) Separately identifiable office/outpatient E/M visits furnished in conjunction with a global procedure; (2) primary care office/outpatient E/M visits for continuous patient care; and (3) certain types of specialist office/outpatient E/M visits. We proposed, but did not finalize, the application of a multiple procedure payment reduction (MPPR) to the first category of visits, to account for overlapping resource costs when office/outpatient E/M visits were furnished on the same day as a 0-day global procedure. To address the shortcomings in the E/M code set in appropriately describing and reflecting resource costs for the other two types of office/outpatient E/M visits, we proposed and finalized the two HCPCS G codes: HCPCS code GCG0X (*Visit complexity inherent to evaluation and management associated with non-procedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established*) which describes the inherent complexity associated with certain types of specialist visits and GPC1X (*Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established*), which describes additional resources associated with primary care visits.

Although we finalized two separate codes, we valued both HCPCS codes GCG0X and GPC1X via a crosswalk to 75 percent of the work and time value of CPT code 90785 (*Interactive complexity (List separately in addition to the code for primary procedure)*). Interactive complexity is an add-on code that may be billed when a psychotherapy or psychiatric service requires more work due to the complexity of the patient, and we believed that 75 percent of its work and time values accurately captured the additional resource costs of primary care office/outpatient E/M visits and certain types of specialty office/outpatient E/M visits when billed with the single, blended payment rate for office/outpatient E/M visit levels 2–4.

In the CY 2019 PFS final rule, we stated that, due to the variation among the types of visits performed by certain specialties, we did not believe that the broad office/outpatient E/M visit code set captured the resource costs associated with furnishing primary care and certain types of specialist visits (FR 83 59638). As we stated above, we believe that the revised office/outpatient E/M visit code set and RUC-recommended values more accurately reflect the resources associated with a typical visit. However, we believe the typical visit described by the revised code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits.

As such, we believe that there is still a need for add-on coding because the revised office/outpatient E/M visit code set does not recognize that there are additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits. However, based on previous public comments and ongoing engagement with stakeholders, we understand the need for the add-on code(s) and descriptor(s) to be easy to understand and report when appropriate, including in terms of medical record documentation and billing. We also clarify that the add-on coding is not intended to reflect any difference in payment based on the billing practitioner's specialty, but rather the recognition of different per-visit resource costs based on the kinds of care the practitioner provides, regardless of their specialty. Therefore, we proposed to simplify the coding by consolidating the two add-on codes into a single add-on code and revising the single code descriptor to better describe the work associated with visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition.

We proposed to revise the descriptor for HCPCS code GPC1X and delete HCPCS code GCG0X. The proposed descriptor for GPC1X appears in Table 36. We solicited comment regarding the proposed changes, particularly the proposed new code descriptor for GPC1X and whether or not more than one code, similar to the policy finalized last year, would be necessary or beneficial.

We have also reconsidered the appropriate valuation for this HCPCS add-on G-code in the context of the revised office/outpatient E/M visit code set and proposed values. Upon further review and in light of the other changes to the office/outpatient E/M visit code set, we believe that valuing the add-on code at 75 percent of CPT code 90785 would understate the additional inherent intensity associated with furnishing primary care and certain types of specialty visits. As CPT code 90785 also describes additional work associated with certain psychotherapy or psychiatric visits, we believe its work

and time values are the most appropriate crosswalk for the revised HCPCS code GPC1X. Therefore, we proposed to value HCPCS code GPC1X at 100 percent of the work and time values for CPT code 90785, and proposed a work RVU of 0.33 and a physician time of 11 minutes. We also proposed that this HCPCS add-on G code could be billed as applicable with every level of office/outpatient E/M visit, and that we would revise the code descriptor to reflect that change. See Table 36 for the changes to the code descriptor. We note that if the CPT Editorial Panel makes any further changes to the office/outpatient E/M visit codes and descriptors, or creates one or more CPT codes that duplicate this add-on code, or if the RUC and/or stakeholders or other public commenters recommend values for these or other related codes, we would consider them through subsequent rulemaking.

TABLE 36: Revaluation of HCPCS Add-on G code Finalized for CY 2021

HCPCS Code	Proposed Code Descriptor Revisions	FR 2019 total time (mins)	FR 2019 Work RVU	Total Time (mins)	Work RVU
GPC1X	*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/ outpatient evaluation and management visit, new or established)*	8.25	0.25	11	0.33

We received public comments on the proposed Simplification, Consolidation and Revaluation of HCPCS codes GCG0X and GPC1X. The following is a summary of the comments we received and our responses.

Comment: Many commenters who rely upon the level 4 and 5 office/outpatient E/M visits to report the majority of their services were very supportive of the consolidation and redefinition of HCPCS codes GCG0X and GPC1X. Commenters agreed with CMS in that, although the revalued office/outpatient E/M visit codes better account for the intensity associated with furnishing these services, there are additional resources associated with primary care and certain types of non-procedural specialty care that are not captured by the revalued codes. Commenters also stated that the revised descriptor was clearer in that it did not allude to certain specialties specifically, but described the work associated with primary care or ongoing care related to a patient's single, serious, or complex chronic condition. Commenters generally supported CMS' proposal to change the level of visits billable with HCPCS code GPC1X from level 2–4 new or established patient visits to all visit levels, although a few commenters stated that it would only be billable with the level 4 and 5 visits because the clinical vignettes associated with those services describe patients with single, serious or complex chronic problem whereas the vignettes associated with the lower level office/outpatient E/M visit codes do not. Commenters also supported the increased work RVU.

Response: We thank the commenters for their support and generally agree with these comments. We note that clinical vignettes are meant to describe a typical patient for purposes of code valuation. Given the wide variety of visit types billable with the office/outpatient E/M visit code set, we do not believe that the value associated with the typical patient accounts for the additional resources associated with primary care or ongoing care related to a patient's single, serious, or complex chronic condition, regardless of the visit level. Therefore, we do not agree that billing HCPCS code GPC1X should be restricted to higher level office/outpatient E/M visits.

Comment: A few commenters recommended that the code descriptor for GPC1X be modified as follows (additions italicized): ''Visit complexity inherent to evaluation and management associated with medical care services that serve as the *first contact* and continuing focal point for all needed health care services *in coordination with others as needed* and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition(s). (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new, or established.).'' These commenters stated that these revisions better capture the work associated with primary care visits. Commenters also requested clarification on what CMS considers to be a ''complex'' or ''serious'' condition, and stated that CMS should issue detailed guidance and clinical scenarios wherein the billing of the GPC1X would be appropriate.

Response: We agree with commenters that the revisions have the potential to improve the accuracy of the code descriptor as it pertains to the primary care services described by HCPCS code GPC1X. We look forward to continued engagement with the public in the development of guidance and, in making this or similar refinements to the code through future rulemaking.

Comment: Other commenters disagreed with CMS' proposal. Many of these commenters, including the RUC, stated that they were supportive of separate payment for an add-on code that would account for additional work associated with ''outlier'' cases of particular clinical intensity but urged CMS to work with CPT and RUC to define and value the service.

Other commenters expressed concern regarding the necessity of HCPCS code GPC1X entirely. A few stated that, given the revaluation of the office/outpatient E/M visit codes, separate payment for certain types of primary care or specialty visits was duplicative and unnecessary. Some commenters also noted that the additional utilization associated with HCPCS code GPC1X further contributed to the redistributive effect of budget neutrality (BN)

adjustment related to revaluing the office/outpatient E/M visit codes, particularly for those specialties who do not routinely furnish office visits.

Response: HCPCS code GPC1X does not describe outlier visits, but visits associated with primary care or care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition(s), which we maintain is qualitatively different from the work accounted for in the revalued office/outpatient E/M visits. As stated previously, we will consider strategies to mitigate the redistributive effects of BN adjustment associated with revaluing of the office/outpatient E/M visit code set as part of future rulemaking.

After considering the comments, we are finalizing the code descriptor for GPC1X as proposed. We are finalizing valuation as proposed. GPC1X will be implemented in CY 2021.

(4) Valuation of CPT Code 99xxx (Prolonged Office/Outpatient E/M)

We proposed to delete to the HCPCS add-on code we finalized last year for CY 2021 for extended office/outpatient E/M visits (GPRO1) and adopt the new CPT code 99XXX. The RUC also provided a recommendation for new CPT code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services*). The RUC recommended 15 minutes of physician time and a work RVU of 0.61. Further, we proposed to accept the RUC recommended values for CPT code 99XXX without refinement.

We solicited comment on these proposals, as well as any additional information stakeholders can provide on the appropriate valuation for these services.

We received public comments on the proposed valuation of CPT code 99xxx. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposed value for CPT code 99XXX. A few commenters recommended a work RVU of 1.17, consistent with the valuation of the HCPCS G-code for additional time finalized in last year's rulemaking, GPRO1.

Response: We note that 99XXX describes 15 minutes of additional time, whereas GPR01 described 30 minutes of additional time. Therefore, we continue to believe that 0.61 is a more accurate work RVU for 99XXX.

After considering the comments, we are finalizing valuation for CPT code 99XXX as proposed.

(5) Implementation Timeframe

We proposed that these policy changes for office/outpatient E/M visits would be effective starting January 1, 2021. We believed this would allow sufficient time for physician and practitioner education and further feedback; changes in clinical workflows, EHRs and any other impacted systems; and corresponding changes that may be made by other payers. In summary, we proposed to adopt the following policies for office/outpatient E/M visits effective January 1, 2021:

- Separate payment for the five levels of office/outpatient E/M visit CPT codes, as revised by the CPT Editorial Panel effective January 1, 2021 and resurveyed by the AMA RUC, with minor refinement. This would include deletion of CPT code 99201 (*Level 1 new patient office/outpatient E/M visit*) and adoption of the revised CPT code descriptors for CPT codes 99202–99215;
- Elimination of the use of history and/or physical exam to select among code levels;
- Choice of time or MDM to decide the level of office/outpatient E/M visit (using the revised CPT interpretive guidelines for MDM);
- Payment for prolonged office/outpatient E/M visits using the new CPT code 99xxx, deletion of HCPCS code GPRO1 (*extended office/outpatient E/M visit*) that we previously finalized for 2021, and no longer recognizing CPT codes 99358–9 for separate payment in association with office/outpatient E/M visits;
- Revise the descriptor for HCPCS code GPC1X and delete HCPCS code GCG0X; and
- Increase in value for HCPCS code GCG1X and allow it to be reported with all office/outpatient E/M visit levels.

We received public comments on the proposed implementation timeframe. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the proposed implementation date of CY 2021, stating that this implementation date would allow adequate time to educate practitioners and their staff, revise electronic health records, and transition clinical workflows, institutional processes and policies, and other aspects of practitioner work that would be impacted by these policy changes. Several commenters suggested that CMS should implement changes for CY 2020 instead of CY 2021. A few commenters suggested that CMS should phase in implementation more gradually, ranging between 18 months to allow electronic health record systems vendors more time to prepare, and 4 or 5 years to mitigate the redistributive impact of the valuation changes.

Response: Given that the CPT coding changes will take effect in 2021, we are finalizing these proposals for January 1, 2021, which is also the implementation timeframe we finalized last year. We believe the delayed implementation to CY 2021 will allow practitioners and electronic health records vendors time to prepare. As stated previously, given that we do not know the magnitude of redistribution resulting from other policies we may adopt through rulemaking before these changes take effect, we believe it would be premature to finalize a strategy in this final rule for addressing redistributive impacts. However, we intend to consider concerns expressed by commenters and address them in future rulemaking.

(6) Global Surgical Packages

In addition to their recommendations regarding physician work, time, and PE for office/outpatient E/M visits, the AMA RUC also recommended adjusting the office/outpatient E/M visits for procedures with post-operative visits included in 10- or 90-day global periods to reflect the changes made to the values for office/outpatient E/M visits. The valuation of most procedures with 10- and 90-day global periods reflect a certain number of post-operative visits that are assumed to typically be furnished by the same practice and specialty as the procedure itself during the global period. While the work involved in these post-operative visits is often valued with reference to RVUs for separately-billed E/M visits, bundled post-operative visit RVUs do not directly contribute a certain number of RVUs to the valuation of procedures with 10- or 90-day global periods.

In the CY 2015 PFS final rule, we discussed the challenges of accurately accounting for the number of visits included in the valuation of 10- and 90-day global packages (79 FR 67548, 67582). We finalized a policy to change all global periods to 0-day global periods, and to allow separate payment for post-operative E/M visits. Our concerns were based on a number of key points including: The lack of sufficient data on the number of visits typically

furnished during the global periods, questions about whether we will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and concerns about how our global payment policies could affect the services that are actually furnished. In finalizing a policy to transform all 10- and 90-day global codes to 0-day global codes in CY 2017 and CY 2018, respectively, to improve the accuracy of valuation and payment for the various components of global packages, including pre- and post-operative visits and the procedure itself, we stated that we were adopting this policy because it is critical that PFS payment rates be based upon RVUs that reflect the relative resources involved in furnishing the services. We also stated our belief that transforming all 10- and 90-day global codes to 0-day global packages would:

- Increase the accuracy of PFS payment by setting payment rates for individual services that more closely reflect the typical resources used in furnishing the procedures;
- Avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner during the global period;
- Eliminate disparities between the payment for E/M services in global periods and those furnished individually;
- Maintain the same-day packaging of pre- and post-operative physicians' services in the 0-day global packages; and
- Facilitate the availability of more accurate data for new payment models and quality research.

Section 523(a) of the MACRA added section 1848(c)(8)(A) of the Act, which prohibited the Secretary from implementing the policy described above, which would have transformed all 10-day and 90-day global surgery packages to 0-day global packages. Section 1848(c)(8)(B) of the Act, which was also added by section 523(a) of the MACRA, required us to collect data to value surgical services. Section 1848(c)(8)(B)(i) of the Act requires us to develop a process to gather information needed to value surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate. Section 1848(c)(8)(B)(iii) of the Act specifies that the Inspector General shall audit a sample of the collected information to verify its accuracy. Section 1848(c)(8)(C) of the Act, which was also added by section 523(a) of the MACRA, requires that, beginning in CY 2019, we must use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS.

Resource-based valuation of individual physicians' services is a critical foundation for Medicare payment to physicians. It is essential that the RVUs under the PFS be based as closely and accurately as possible on the actual resources used in furnishing specific services to make appropriate payment and preserve relativity among services. For global surgical packages, this requires using objective data on all of the resources used to furnish the services that are included in the package. Not having such data for some components may significantly skew relativity and create unwarranted payment disparities within the PFS. The current valuations for many services valued as global packages are based upon the total package as a unit rather than by determining the resources used in furnishing the procedure and each additional service/visit and summing the results. As a result, we do not have the same level of information about the components of global packages as we do for other services. To value global packages accurately and relative to other procedures, we need accurate information about the resources—work, PEs and malpractice—used in furnishing the procedure, similar to what is used to determine RVUs for all services. In addition, we need the same information on the postoperative services furnished in the global period (and pre-operative services the day before for 90-day global packages).

In response to the MACRA amendments to section 1848(c)(8) of the Act, CMS required practitioners who work in practices that include 10 or more practitioners in Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island to report using CPT 99024 on post-operative visits furnished during the global period for select procedures furnished on or after July 1, 2017. The specified procedures are those that are furnished by more than 100 practitioners and either are nationally furnished more than 10,000 times annually or have more than $10 million in annual allowed charges.

RAND analyzed the data collected from the post-operative visits through this claim- based reporting for the first year of reporting, July 1, 2017 through June 30, 2018. They found that only 4 percent of procedures with 10-day global periods had any post-operative visits reported. While 71 percent of procedures with 90-day global periods had at least one associated post-operative visit, only 39 percent of the total post-operative visits expected for procedures with 90-day global periods were reported. (A complete report on this is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html.*)

In addition to the claims-based data collection, RAND collected data on the level of visits. They began with an attempt to collect data via a survey from all specialties as described in the 2017 final rule. Given the low rate of response from practitioners, we narrowed the scope and focused on three high-volume procedures with global periods that were common enough to likely result in a robust sample size: (1) Cataract surgery; (2) hip arthroplasty; and (3) complex wound repair. A total of 725 physicians billing frequently for cataract surgery, hip arthroplasty, and complex wound repair reported on the time, activities, and staff involved in 3,469 visits. Our findings on physician time and work from the survey were broadly similar to what we expected based on E/M visits in the Time File for cataract surgery and hip replacement and somewhat different for complex wound repair. It should be noted that the time and work values used for this comparison were for 2018 E/M visits. (For the complete report, see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html.*)

The third report in the series looks at ways we could consider revaluing procedures using the collected data. To provide us with estimates to frame a discussion, RAND modeled how valuation for procedures would change by adjusting work RVUs, physician time, and direct PE inputs based on the difference between the number of post-operative visits observed via claims-based reporting and the expected number of post-operative visits used during valuation. RAND looked at three types of changes: (1) Updated work RVUs based on the observed number of post-operative visits measured four ways (median, 75th percentile, mean, and modal observed visits); (2) Allocated PE RVUs reflecting direct PE inputs updated to reflect the median number of reported post-operative visits; and (3) Modeled total RVUs reflecting (a) updated work RVUs, (b) updated physician time, and (c) updated

direct PE inputs, and including allocated PE and malpractice RVUs. This report is designed to inform further conversations about how to revalue global procedures. (For the complete report, see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html*.) We provided the public and stakeholders the data we had available with the proposed rule, and asked that they provide input on an appropriate approach to using these data to revalue global surgical procedures. We will continue to study and consider alternative ways to address the values for these services.

We received public comments on the impact of the new E/M coding and valuations on global surgical packages and on the reports and other information on revaluing global surgical packages that we made available with the proposed rule. The following is a summary of the comments we received and our responses.

Comment: Most commenters objected to not using the proposed new E/M coding and valuations to revise the values for global surgery packages. The commenters stated that failure to use the new E/M coding and values for global services will disrupt the relativity in the PFS, create specialty differences and could violate the MACRA section 523(a) statutory requirements. Most commenters objected to our not proposing to adopt the AMA RUC recommendations to apply revised values for E/M office visits in global surgery procedures. They stated that not adopting the RUC recommendations interferes with relativity because we proposed to apply the RUC-recommended E/M values to stand-alone E/M services, but not to the E/M services that are included in global surgical packages. Commenters noted that in the past, CMS has aligned changes in valuation of stand-alone office visits with valuation of the office visits in the surgical global period so that each time the value for separately billed office visits was changed, corresponding changes were made to the value of visits for all global surgery packages. In addition, some commenters stated that, by failing to adopt all of the RUC-recommended work and time values for the revised office visit E/M codes, including the recommended adjustments to the 10- and 90-day global codes, CMS is implementing these values in an arbitrary and piecemeal fashion. Some commenters stated that applying the RUC-recommended E/M values to stand-alone E/M services, but not to the E/M services that are included in the global surgical package, would result in disruption to the relativity between codes across the Medicare PFS. A number of commenters also stated that failing to adjust the global codes to reflect adjustments to separately billable E/M services is tantamount to paying some physicians less for providing the same E/M services, in violation of the law.

Response: Relativity is an important concept we consider heavily when establishing values for services under the PFS. To maintain relativity in the past, we had adjusted values for global surgery procedures when we updated values for E/M visits because we did not have information to suggest that it might not be appropriate to do so. However, there are now important, unresolved questions regarding how post-operative visits included in global surgery codes should be valued relative to stand-alone E/M visit analogues. Specifically, it is unclear whether it would be appropriate to use a building-block approach to increase the valuation for global surgical packages in a way that could disrupt potentially more accurate estimates of total work for procedures with global periods from magnitude estimation. Furthermore, given the information described above on E/M services furnished as part of global surgery services, we have questions about the appropriate number of E/M services reflected in the values for global surgery procedures. If the number of E/M services for global codes is not appropriate, adopting the AMA RUC-recommended values for E/M services in global surgery codes would exacerbate rather than ameliorate any potential relativity issues. Therefore, we are not adopting the RUC recommendation to apply revised values for E/M services to the global surgery codes at this time.

Section 1848(c)(8)(C) of the Act, as added by section 523a of the MACRA, requires CMS to use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS. We believe it is important to avoid contributing further to the potential misvaluation of global surgical procedures. Reflexively adding revised E/M work RVUs to values for global codes as recommended by the RUC and other commenters could potentially result in inappropriate shifts in relativity under the PFS, and the associated BN adjustment could result in potentially inappropriate adjustments to payment rates for services without global periods, such as separately-billed E/M visits. Given that the information we have gathered to date as required by section 1848(c)(8)(B)(i) of the Act, as well as the conclusions of past OIG studies, suggests that the values for E/M services typically furnished in global surgery periods are overstated in the current valuations for global surgery codes, we do not believe it would be appropriate to amplify the effects of any such overvaluation by increasing the values of included E/M services while we continue to look into the information and develop appropriate solutions.

Comment: Commenters raised concerns about the generalizability of the claims data we collected on post-operative visits since it was only collected from practices with 10 or more practitioners in 9 states. One commenter stated that the AMA 2018 Physician Practice Benchmark Survey indicated that 54 percent of physicians are in practices with fewer than 10 physicians. They added that, for surgical specialties, 64 percent of physicians are in practices with fewer than 10 physicians. Commenters expressed a related concern that the definition of ''practice'' used in the reporting of post-operative visits caused confusion and decreased reporting. Further, commenters expressed concern that some physicians may not have been aware of the reporting requirement, and therefore, some post-operative visits were not reported. One commenter noted that using CPT 99024 to report post-operative visits contradicts specialty society coding education, and some practices encountered difficulties reporting the zero-charge CPT 99024 as attempts to report the code in many practices and EHR systems are blocked by the software.

Response: We believe that the newly-collected post-operative visit data significantly improves our understanding of which bundled post-operative visits are actually furnished during global periods, beyond estimates provided by the AMA RUC and specialty society surveys. CMS chose to limit reporting to a random sample of 9 states and to exclude practices with less than 10 practitioners because of concerns from the physician community about reporting burden, which might be particularly high for smaller practices. Some commenters have now suggested that the scope of our required reporting may be inadequate. We can consider for the future whether requiring reporting for smaller practices and throughout the country would give us better data. We also note that, although we have authority to do so, we chose not to penalize practitioners who did not report, but we could also reevaluate this decision if the current reporting rates are insufficient.

Comment: Commenters disagreed with the conclusion in the RAND report that only 39 percent of expected post-operative visits following procedures with 90-day global periods and only 4 percent of expected post-operative visits following procedure with 10-day global periods were actually performed. Commenters objected to counting all non-occurring visits as ''no'' visits as some visits were not reported. Relatedly, commenters raised many concerns with the methodology used in the RAND analyses. These include:

- Revaluations from the RUC have made the data outdated.
- Potential flaws in the way procedures were matched to reported 99024 codes.
- Disagreement with the definition of ''robust reporters'' used in the sensitivity analyses.
- Possible bias from the use of half-visits from the time file.
- Reporting of procedures with 10-day global periods are dominated by HCPCS codes 17000, 17004 and 17110, which are not representative of all procedures.
- Inclusion of separately-billed E/M services to provide post-operative care could account for the gap between observed and expected visits.

Response: The RAND results focus on the share of expected post-operative visits that were reported to CMS. It is true that the absence of a reported visit does not necessarily mean that a post-operative visit did not occur. However, apart from required reporting, we have no way to know whether a visit occurred. For some specialties, including hand surgery, orthopedic surgery, vascular surgery, ophthalmology, neurosurgery, urology, plastic and reconstructive surgery, dermatology and general surgery, 85 percent or more of practitioners who were expected to report post-operative visits relating to global surgical services reported at least some visits. We can only assume the visits that are furnished are being reported.

The RAND report includes results from many sensitivity analyses that aim to address several methodological concerns raised by some commenters, and particularly concerns related to potentially incomplete reporting. While different sensitivity approaches slightly increase or decrease the number of reported post-operative visits we would expect to see, none results in findings that differ substantially from the report's main conclusions that a small share of expected post-operative visits for procedures with 10-day global periods, and less than half of expected post-operative visits for procedure with 90-day global periods, appear to actually occur. RAND will be issuing a report in response to each of these methodological concerns later this year. This report will also be posted on the CMS website.

Comment: MedPAC supported CMS' decision to not adopt the RUC's recommendation that CMS adjust the work RVUs for postoperative E/M visits that are part of surgical codes with 10-day and 90-day global periods. MedPAC cited evidence that 10-day and 90-day global surgical codes are overvalued. Several other commenters agreed that we should not adjust values for the global surgery codes to reflect revised values for E/M visits. For example, one commenter stated, ''[W]e believe it would be imprudent to adjust the E/M component [of global surgery codes] because of any changes to the values of stand-alone office/outpatient visit codes 99201–99215 and we support CMS' decision in this regard.'' Another commenter expressed support for CMS' ''efforts to collect this information and ensure an appropriate number and type of E/M codes bundled with the 10-day and 90-day globals.''

Response: We agree that it would be imprudent at this point to adjust the values for surgical codes with 10- and 90-day global periods to reflect the values for stand-alone E/M visits.

After considering the comments, we are not making changes in the values of global surgery procedures to reflect changes we are making in this final rule beginning in CY 2021 to coding and values for stand-alone E/M services. We anticipate continuing to assess and develop an approach to revaluing global surgery procedures, including the associated post-operative visits. We appreciate all the comments on the three RAND reports and we will study them as we go forward. For the specialty societies that expressed concern that our current method does not accurately account for the data, we welcome submissions on other methods of gathering the data or ways to tabulate the results.

c. Comment Solicitation on Revaluing the Office/Outpatient E/M Visit Within TCM, Cognitive Impairment Assessment/Care Planning and Similar Services

In the CY 2020 PFS proposed rule, we recognized that there are services other than the global surgical codes for which the values are closely tied to the values of the office/outpatient E/M visit codes, such as transitional care management services (CPT codes 99495, 99496); cognitive impairment assessment and care planning (CPT code 99483); certain ESRD monthly services (CPT codes 90951 through 90961); the Initial Preventive Physical Exam (G0438) and the Annual Wellness Visit (G0439). We stated that, in future rulemaking, we may consider adjusting the RVUs for these services and we sought public input on such a policy. We noted that, unlike the global surgical codes, many of these services always include an office/outpatient E/M visit(s) furnished by the reporting practitioner as part of the service, and therefore, it may be appropriate to adjust their valuation commensurate with any changes to the values for the revised codes for office/outpatient E/M visits. While some of these services do not involve an included E/M visit, we valued them using a direct crosswalk to the RVUs assigned to an office/outpatient E/M visit(s), and for this reason they are closely tied to values for office/outpatient E/M visits.

We also sought comment on whether or not the public believes it would be necessary or beneficial to make systematic adjustments to other related PFS services to maintain relativity between these services and office/outpatient E/M visits. We were particularly interested in whether it would be beneficial or necessary to make corresponding adjustments to E/M codes describing visits in other settings, such as home visits, or to codes describing more specific kinds of visits, like counseling visits. For example, CPT code 99348 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family*) is commonly used to report home visits, and like CPT code 99214, the code describes approximately 45 minutes of time with the patient and has a work RVU of 1.56. Under the proposal to increase the work RVU of CPT code 99214 from 1.5 to 1.92, the proportional value of CPT code 99348 would decrease relative to the work RVU for CPT code 99214. To maintain the same proportional value to CPT code 99214, the work RVU for CPT code 99348 would need to increase from 1.56 to

2.00. We understand that certain other services, such as those that describe ophthalmological examination and evaluation, as well as psychotherapy visit codes, are used either in place of or in association with office/outpatient visit codes.

For example, CPT code 92012 (*Ophthalmological services: Medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient*) currently has a work RVU of 0.92. Under the proposal to increase the work RVU of CPT code 99213 from 0.97 to 1.30, the proportional value of CPT code 92012 would decrease relative to the work RVU for CPT code 99213, as both codes describe around 30 minutes of work. To maintain the same proportional value to CPT code 99213, the work RVU for CPT code 92012 would need to increase from 0.92 to 1.23. Similarly, behavioral health professionals report several codes to describe psychiatric diagnostic evaluations and visits they furnish. When furnished with an E/M service, practitioners report psychotherapy add-on codes instead of stand-alone psychotherapy codes that would otherwise be reported. Because the overall work RVUs for the combined service, including the value for the office/outpatient visit code, would increase under the proposal, we are interested in comments regarding whether or not it would be appropriate to reconsider the value of the psychotherapy codes, as well as the psychiatric diagnostic evaluations relative to the proposed values for the office/outpatient visit codes. Under the proposed revaluation of the office/outpatient E/M visits, the proportional value of CPT code 90834 (*Psychotherapy, 45 minutes with patient*) would decrease relative to work RVUs for CPT code 99214 plus CPT code 90836. The current work RVU for CPT code 99214 when reported with CPT code 90836 is 3.40 (1.90 + 1.50) and the current work RVU for CPT code 90834 is 2.0. Under the proposed revaluation of the office/outpatient E/M visits, the combined work RVU for CPT codes 99214 and 90836 would be 3.82 (1.90 + 1.92). To maintain the proportionate difference between these services, the work RVU for CPT code 90834 would increase from 2.00 to 2.25. Based on these three examples, we sought public comment on whether we should make similar adjustments to E/M codes in different settings, and other types of visits, such as counseling services.

Comment: Many commenters supported some degree of revaluation of non-global surgical codes that include one or more bundled office/outpatient visits (such as TCM and the ESRD MCPs), E/M visits in other settings (such as inpatient or home visits), other E/M services (such as care planning for patients with cognitive impairment), and/or non-E/M office visits (such as the ophthalmology visit codes.)

Some commenters suggested specific revaluations. Commenters recommended that CMS revalue the ophthalmological visits to maintain relativity with the office/outpatient E/M services. This commenter recommended a new RVU of 0.88 for CPT code 92002, an RVU of 2.05 for CPT code 92004, and RVU of 1.23 for CPT code 92012, and an RVU of 1.82 for CPT code 92014. Commenters also suggested a work RVU of 1.60 for CPT code 99283, and RVU of 2.74 for CPT code 99284, and an RVU of 4.00 for CPT code 99285 to maintain relativity between these services and the office/outpatient E/M visits.

Other commenters suggested making a single adjustment to the E/M visits in other settings to maintain relativity between these services and the revalued office/outpatient E/M visits. Many of these commenters also requested that CMS make similar revisions to the code definitions and documentation requirements for those services. Commenters also supported updating the payment rates for the ESRD MCP codes, noting that a similar adjustment had not been made to those codes when the office/outpatient E/M visits were revalued in the past.

Response: We thank commenters for their thorough recommendations and look forward to considering these recommendations for future rulemaking.

III. Other Provisions of the Proposed Regulations

A. Changes to the Ambulance Physician Certification Statement Requirement

Under our ongoing initiative to identify Medicare regulations that are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, we proposed to revise §§ 410.40 and 410.41. Importantly, in the proposed rule (84 FR 40680), we first clarified that these requirements apply to ambulance providers, as well as suppliers. We stated that the revisions would give certain clarity to ambulance providers and suppliers regarding the physician or non-physician certification statement and add staff who may sign certification statements when the ambulance provider or supplier is unable to obtain a signed statement from the attending physician.

1. Exceptions to Certification Statement Requirement

Under section 1861(s)(7) of the Act, ambulance services are covered where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Currently, § 410.40(d) specifies the medical necessity requirements for both nonemergency, scheduled, repetitive ambulance services and nonemergency ambulance services that are either unscheduled or that are scheduled on a non-repetitive basis. In the final rule with comment period that appeared in the January 25, 1999 **Federal Register** (64 FR 3637) (hereinafter referred to as the ''January 25, 1999 final rule with comment period''), we stated that a physician certification statement (PCS) must be obtained as evidence that the attending physician has determined that other means of transportation are contraindicated and that the transport is medically necessary (64 FR 3639). In the final rule with comment period that appeared in the February 27, 2002 **Federal Register** (67 FR 9100) (hereinafter referred to as the ''February 27, 2002 final rule with comment period''), we added that a certification statement (hereinafter referred to as ''non-physician certification statement'') could be obtained from other authorized staff should the attending physician be unavailable. (67 FR 9111)

We stated in the proposed rule (84 FR 40680) that currently there are no circumstances, other than those specified at § 410.40(d)(3)(ii) and (iv), granting exceptions to the need for a PCS or non-physician certification statement, and that we have received feedback from ambulance providers, suppliers, and their industry representatives (''stakeholders'') that various situations exist where the need for a PCS or non-physician certification is excessive, or at least redundant to similar existing documentation requirements. Two of the most prominent circumstances identified by the stakeholders include interfacility transports (IFTs), commonly referred to as hospital-to-hospital transports, and specialty care transports (SCTs), and stakeholders have requested that we incorporate additional exceptions into the regulatory framework.

As we discussed in the proposed rule (84 FR 40680 through 40681), upon reviewing the need for a PCS and non-physician certification statement, stakeholders' concerns, and our commitment to reducing the burden placed on providers and suppliers, we have determined that instead of

incorporating additional exceptions, our efforts would be better served by minorly altering the structure of the existing regulatory framework. We stated in the proposed rule that these changes are intended to maximize flexibility for ambulance providers and suppliers to obtain the requisite certification statements and maintain the focus on the determination that other means of transportation are contraindicated and that the transport is medically necessary.

To accomplish this, we proposed to add a new paragraph (a) in § 410.40 in which we would define both PCSs, as well as non-physician certification statements. Therefore, we proposed to redesignate existing paragraph (a) ''Basic rules'' as paragraph (b) and redesignate the remaining paragraphs, respectively. Most significantly, paragraph (d) ''Medical necessity requirements'' will be redesignated as paragraph (e).

We stated in the proposed rule (84 FR 40681) that for paragraph (a), the two definitions, PCSs and non-physician certification statements, would clarify that: (1) The focus is on the certification of the medical necessity provisions contained in newly redesignated paragraph (e)(1); and (2) the form of the certification statement is not prescribed, thus affording maximum flexibility to ambulance providers and suppliers. We stated that since the two definitions would incorporate the requirement to obtain a certification of medical necessity, we proposed a conforming change to newly redesignated paragraph (e)(2) to remove the language requiring that an order certifying medical necessity be obtained.

As we stated in the proposed rule, we have repeatedly been told by stakeholders that there are ample opportunities for ambulance providers and suppliers to convey the information required in the certification statement. Stakeholders have mentioned, for example, that for transports such as IFTs and SCTs other requirements of federal, state, or local law require them to obtain other documentation, such as Emergency Medical Treatment & Labor Act (EMTALA) forms and medical transport forms, that serve the same purpose as the PCS or non-physician certification statement. There is every likelihood that other ambulance transports require similarly styled documentation that likewise could serve the same purpose.

To be clear, our regulations have never prescribed the precise form or format of this required documentation. As we discussed in the proposed rule, to satisfy the requirements of section 1861(s)(7) of the Act, ambulance providers' and suppliers' focus should be on clearly documenting the threshold determination that other means of transportation are contraindicated and that the transport is medically necessary. We stated that the precise form or format by which that information is conveyed has never been prescribed. We further stated that our aim here is to ensure that ambulance providers and suppliers understand they have flexibility in the form by which they convey the requirements of proposed § 410.40(e), so long as that threshold determination is clearly expressed.

We stated in the proposed rule that the definition of non-physician certification statement in § 410.40(a) would incorporate the existing requirements that apply when an ambulance provider or supplier is unable to obtain a signed PCS from the attending physician and, instead, obtains a non-physician certification statement, including: (1) That the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished; (2) the employment-related requirements; and (3) the specific staff that can sign in lieu of the attending physician. We stated that included within the definition of non-physician certification statement, and as further discussed below, is an expansion of the list of staff who may sign when the attending physician is unavailable. In light of the staff being listed as part of the definition of non-physician certification statement at § 410.40(a), we proposed a corresponding change to proposed and newly redesignated paragraph (e)(3)(iii) to remove the reference to the staff currently listed within the paragraph. Moreover, in paragraphs (e)(3)(i) and (iv), we proposed changes to refer to the newly redesignated paragraph (e), and in paragraph (e)(3)(v), we proposed changes to refer to the newly defined terms in paragraph (a), specifically the physician or non-physician certification statement. Lastly, we also proposed a corresponding change to § 410.41(c)(1) to add that ambulance providers or suppliers must indicate on the claims form that, ''when applicable, a physician certification statement or non-physician certification statement is on file.''

In the CY 2013 PFS final rule with comment period (77 FR 69161), we stated that the Secretary is the final arbiter of whether a service is medically necessary for Medicare coverage. We stated in the proposed rule that we believe that the proposed changes would better enable contractors to establish the medical necessity of these transports by focusing more on the threshold medical necessity determination as opposed to the form or format of the documentation used. We further stated that we did not anticipate that this clarification will alter the frequency of claim denials.

In 2018, 68.9 percent of improper payments in non-emergency transport was due to insufficient documentation. Although we know the ambulance certification statement is a source of documentation error, we are unable to determine if clarifying that there is no specific form or format for the certification statement will lead to significantly fewer denials. Similarly, we are unable to determine whether adding to the list of non-physicians that may sign a certification statement will lead to significantly fewer denials. The impact primarily will afford providers increased flexibility in completing the form. We believe that claims denied for technical documentation issues currently are likely appealed and overturned in the supplier/provider's favor if the ambulance transport was indeed medically necessary. Therefore, although we believe the clarifications could result in fewer claims being denied, it is unlikely to be a statistically significant change.

2. Addition of Staff Authorized To Sign Non-Physician Certification Statements

In the January 25, 1999 final rule with comment period (64 FR 3637), we finalized language at § 410.40 to require ambulance providers or suppliers, in the case of nonemergency unscheduled ambulance services (§ 410.40(d)(3)) to obtain a PCS. In that rule, we explained that: (1) Nonemergency ambulance service is a Medicare service furnished to a beneficiary for whom a physician is responsible, therefore, the physician is responsible for the medical necessity determination; and (2) the PCS will help to ensure that the claims submitted for ambulance services are reasonable and necessary, because other methods of transportation are contraindicated (64 FR 3641). We further stated that we believed the requirement would help to avoid Medicare payment for unnecessary ambulance services that are not medically necessary even though they may be desirable to beneficiaries. However, in that final rule with comment period, we also addressed the ability of ambulance providers or suppliers to obtain a written order from the beneficiary's attending physician within 48 hours after the transport to avoid unnecessary delays. We agreed with stakeholders that while it is

reasonable to expect that an ambulance supplier could obtain a pretransport PCS for routine, scheduled trips, it is less reasonable to impose such a requirement on unscheduled transports, and that it was not necessary that the ambulance suppliers have the PCS in hand prior to furnishing the service. To avoid unnecessary delays for unscheduled transports, we finalized the requirement that required documentation can be obtained within 48 hours after the ambulance transportation service has been furnished.

In the February 27, 2002 final rule with comment period (67 FR 9111), we noted that we had been made aware of instances in which ambulance suppliers, despite having provided ambulance transports, were, through no fault of their own, experiencing difficulty in obtaining the necessary PCS within the required 48-hour timeframe. We stated that the 48-hour period remained the appropriate period of time, but created alternatives for ambulance providers and suppliers unable to obtain a PCS. We finalized an alternative at § 410.40(d)(3)(iii) where ambulance providers and suppliers unable to obtain a PCS from the attending physician could obtain a signed certification (*not* a physician certification statement) from certain other staff. At that time, we identified several staff members, including a physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), and a discharge planner as staff members able to sign such a non-physician certification statement. The only additional constraints are: (1) That the staff be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported; and (2) that the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished.

We stated in the proposed rule (84 FR 40682) that in the intervening years, we have received feedback from stakeholders that other staff, such as licensed practical nurses (LPNs), social workers, and case managers, should be included in the list of staff that can sign a certification statement. Similar to the currently designated staff, we stated that we now believe that LPNs, social workers, and case managers who have personal knowledge of a beneficiary's condition at the time ambulance transport is ordered and the service is furnished have a skill set largely equal or similar to the other staff members. Thus, we proposed as part of the new definition of non-physician certification statement at § 410.40(a)(2)(iii) to add LPNs, social workers, and case managers to the list of staff who may sign a certification statement when the ambulance provider or supplier is unable to obtain a signed PCS from the attending physician. As with the staff currently listed in § 410.40(d)(3)(iii), LPNs, social workers, and case managers would need to be employed by the beneficiary's attending physician or the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported, and have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished. We also requested comments on whether other staff should be included in this regulation, and requested that commenters identify such staff's licensure and position and the reason it would be appropriate for such staff to sign a certification statement.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our changes to the ambulance certification requirements, including the addition of licensed practical nurses, social workers, and case managers to the list of non-physician staff who are authorized to sign a certification statement when a statement cannot be obtained from the attending physician. One commenter noted that CMS should monitor the new provisions closely to ensure that enforcement is fair, consistent, and expected and the new approach is not abused.

Response: We agree that the new provisions must be fairly and consistently applied. Through our contractors, we will focus on ensuring a fair and consistent application of the new requirements so that the requirements are not subject to abuse.

Comment: One commenter recommended that a licensed non-physician staff member should be authorized to sign a certification statement for all emergency and nonemergency cases and that adding an additional layer of bureaucracy does not increase quality, but does increase cost.

Response: We do not currently require a certification statement for emergency ambulance transport, and did not propose to add such a requirement for emergency ambulance transport as it would, among other things, increase documentation burden and costs. We continue to believe that requiring a certification statement for non-emergency ambulance transports is necessary. Of note, the certification assists our efforts in combating fraud, waste and abuse.

Comment: One commenter supported the ''proposal to eliminate the PCS as a requirement for hospital-to-hospital transports,'' and requested confirmation that CMS will not burden ambulance service providers and suppliers with having to obtain the other documents, for example, transfer forms and/or EMTALA forms, that can be used in lieu of the PCS and to clarify that if a PCS is not required for interfacility transports, then ambulance service providers and suppliers will not be required to obtain a certificate of mailing (or proof of mailing).

Response: To be clear, we did not propose the elimination of the PCS as a requirement for hospital-to-hospital transports. Rather, we clarified that the precise form or format of the certification statement is not prescribed, thus increasing ambulance suppliers' and providers' flexibility to comply with the certification statement requirements. Also, the steps we have taken to clarify the regulations do not obviate a provider's or supplier's responsibility to submit required documentation upon request to Medicare review contractors, which may request documentation from the supplier or provider to evaluate eligibility, coverage, medical necessity, and other reimbursement-related factors.

Comment: One commenter questioned if CMS would consider the completion of a non-physician certification statement by nursing staff in the emergency department as compliant with the regulatory requirements, if the treating physician is unavailable due to treatment of another patient in the Emergency Department.

Response: The scope of this rule is to clarify the requirements associated with the form and content of the physician certification statement and the non-physician certification statement along with adding additional staff members who may, under the appropriate circumstances, sign a non-physician certification statement. Although this scenario could be acceptable should the criteria set forth in the regulations be met, specific fact-based scenarios should be discussed with the appropriate Medicare Administrative Contractor.

Comment: One commenter recommended CMS make additional changes, including modernizing and streamlining the 855B Ambulance Enrollment form, eliminating the duplicative requirements for patient

signatures, and modernizing the revocation process for suppliers' and providers' ability to bill Medicare.

Response: These recommendations are outside the scope of the proposed changes.

Comment: One commenter noted that the changes will do very little to lessen the unnecessary burden that the PCS requirement imposes on ambulance providers and suppliers every day and that CMS, instead, should ''eliminate this useless exercise in chasing paper'' and alleged that the PCS carries ''no weight.'' This same commenter recommended that CMS add several additional staff members who can sign the non-physician certification statement, including licensed vocational nurses (LVNs), advanced practice registered nurses (APRNs), paramedics not functioning as an employee of the ambulance provider or supplier furnishing the ambulance services for which payment is claimed, physical therapists, occupational therapists, psychiatrists and psychologists.

Response: Although we understand the commenter's concern regarding burden, we disagree that the certification statements are a useless exercise or that they carry no weight. We specifically noted within the proposed rule that the changes were intended to maximize flexibility for ambulance providers and suppliers to obtain the requisite certification statements and maintain the focus on the determination that other means of transportation are contraindicated and that the transport is medically necessary. We believe the clarifications are in line with our intended outcome and the certification statements serve an important role in preventing and combating fraud, waste and abuse. The clarifications to the certification statement requirements will, in fact, reduce burden by clearly conveying that redundant certification statements need not be submitted and as a result of other non-physician staff members being authorized to sign non-physician certification statements. Moreover, while we appreciate the information regarding other staff members who could sign a non-physician certification, we are not adding additional staff members at this time. Of note, psychiatrists, as physicians are already included as staff who can sign the physician certification statement. For the remaining suggested positions, we appreciate the suggestions regarding additional staff who could sign the non-physician certification and will consider the suggestions in future rulemaking.

Comment: One commenter suggested CMS correct what the commenter believed is an inaccurate statement regarding the prior existence or use of the term ''non-physician certification statement in that CMS had not previously used that term. The same commenter also recommended several other modifications to promote consistency and readability within the regulations, including: (1) Deleting superfluous language in § 410.40(e)(3)(i) related to the certifying of medical necessity since the phrase is already included as part of the newly proposed definition of PCS in paragraph (a); (2) that CMS should change the words ''procedure codes'' to ''modifiers'' in proposed § 410.41(c)(1) as the term ''modifiers'' more accurately refers to origin and destination indicators; and (3) that CMS add references to both suppliers and providers in § 410.41(c) and (c)(2), that refer to both physician certification statements and non-physician certification statements in (c)(1) and change the word ''or'' to ''a'' in newly proposed § 410.40(e)(3)(iii) preceding the phrase ''non-physician certification statements must be obtained.''

Response: We appreciate the commenter's observation that we did not previously use the term ''non-physician certification statement,'' but we merely used the term to facilitate our efforts to more clearly convey the distinction we are attempting to account for within the regulations, namely that a certification statement can—in certain limited circumstances—be signed by a staff member who is not a physician. We believe that use of the term non-physician certification statement is particularly relevant since we are adding even more positions to the list of personnel who can sign these statements. We believe that the clarified terminology allows better process accountability so a physician's signature is not mistaken with other personnel only sometimes eligible to sign, which should aid in combatting potential fraud and abuse. Additionally, with regard to (1) deleting superfluous language in § 410.40(e)(3)(i) related to the certifying of medical necessity since the phrase is already included as part of the newly proposed definition of PCS in paragraph (a), we agree this language is no longer necessary in light of the definition and are deleting it. Regarding item (2) that we should change the words ''procedure codes'' to ''modifiers'' in proposed § 410.41(c)(1) as the term ''modifiers'' more accurately refers to origin and destination indicators, we appreciate the commenter's suggestion and may propose alternative language to address this in future rulemaking. Finally, we agree and are implementing the recommendations in (3) that we add references to both suppliers and providers in § 410.41(c) and (c)(2) and noted an additional need for reference to both in § 410.40(e)(3)(iv), refer to both the physician certification statement and non-physician certification statement in § 410.41(c)(1), and change the word ''or'' to ''a'' in newly proposed § 410.40(e)(3)(iii) preceding the phrase ''non-physician certification statements must be obtained.''

After consideration of the comments received, for the reasons set forth in the proposed rule and in this final rule, we are finalizing our proposed revisions to §§ 410.40 and 410.41 with the modifications discussed above. In addition, we are making conforming/technical changes to update cross-references in §§ 409.27 and 414.605, as necessitated by the redesignation of paragraphs in § 410.40.

B. Establishment of a Medicare Ground Ambulance Data Collection System

1. Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a GAF, and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base rate and/or mileage rate. The two permanent add-on payments are: (1) A 50 percent increase in the standard mileage rate for ground ambulance transports that originate in rural areas where the travel distance is between 1 and 17 miles; and (2) a 50 percent increase to both the base and mileage rate for rural air ambulance transports. The three temporary add-on payments are: (1) A 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2 percent increase to

the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in ''super rural'' areas. Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Statutory Requirement for Ground Ambulance Providers and Suppliers To Submit Cost and Other Information

Section 50203(b) of the BBA of 2018 added a new paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. Such system must be designed to collect information: (1) Needed to evaluate the extent to which reported costs relate to payment rates under the AFS; (2) on the utilization of capital equipment and ambulance capacity, including information consistent with the type of information described in section 1121(a) of the Act; and (3) on different types of ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in section 1834(l)(12) of the Act (super rural areas).

Section 1834(l)(17)(B)(i) of the Act requires the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system, including the representative sample defined at clause (ii).

Under section 1834(l)(17)(B)(ii) of the Act, not later than December 31, 2019, for the data collection for the first year and for each subsequent year through 2024, the Secretary must determine a representative sample to submit information under the data collection system. The sample must be representative of different types of ground ambulance providers and suppliers (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas), and not include an individual ground ambulance provider or supplier in the sample for 2 consecutive years, to the extent practicable.

Section 1834(l)(17)(C) of the Act requires that for each year, a ground ambulance provider or supplier identified by the Secretary in the representative sample as being required to submit information under the data collection system for a period for the year must submit to the Secretary the information specified under the system in a form and manner, and at a time specified by the Secretary.

Section 1834(l)(17)(D) of the Act requires that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. A hardship exemption to the payment reduction is authorized under section 1834(l)(17)(D)(iii) of the Act, which provides that the Secretary may exempt a ground ambulance provider or supplier from the payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the ground ambulance provider or supplier to submit such information in a timely manner for the specified period. Lastly, section 1834(l)(17)(D)(iv) of the Act requires the Secretary to establish an informal review process under which a ground ambulance provider or supplier may seek an informal review of a determination that the provider or supplier is subject to the payment reduction.

Section 1834(l)(17)(E)(i) of the Act allows the Secretary to revise the data collection system as appropriate and, if available, taking into consideration the report (or reports) that the Medicare Payment Advisory Commission (MedPAC) will submit to Congress. Section 1834(l)(17)(E)(ii) of the Act specifies that, to continue to evaluate the extent to which reported costs relate to payment rates under section 1834(l) of the Act and other purposes as the Secretary deems appropriate, the Secretary shall require ground ambulance providers and suppliers to submit information for years after 2024, but in no case less often than once every 3 years, as determined appropriate by the Secretary.

As required by section 1834(l)(17)(F) of the Act, not later than March 15, 2023, and as determined necessary by MedPAC, MedPAC must assess, and submit to Congress a report on, information submitted by providers and suppliers of ground ambulance services through the data collection system, the adequacy of payments for ground ambulance services and geographic variations in the cost of furnishing such services. The report must contain the following:

- An analysis of information submitted through the data collection system;
- An analysis of any burden on ground ambulance providers and suppliers associated with the data collection system;
- A recommendation as to whether information should continue to be submitted through such data collection system or if such system should be revised by the Secretary, as provided under section 1834(l)(17)(E)(i) of the Act; and
- Other information determined appropriate by MedPAC.

Section 1834(l)(17)(G) of the Act requires the Secretary to post information on the results of the data collection on the CMS website, as determined appropriate by the Secretary.

Section 1834(l)(17)(H) of the Act requires the Secretary to implement the provisions of section 1834(l)(17) of the Act through notice and comment rulemaking.

Section 1834(l)(17)(I) of the Act provides that the Paperwork Reduction Act (Title 44, Chapter 35 of the U.S. Code) does not apply to collection of information required under section 1834(l)(17) of the Act.

Section 1834(l)(17)(J) of the Act provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the data collection system or identification of respondents.

We note that while the requirements of section 1834(l)(17) of the Act are specific to ground ambulance organizations, many stakeholders have expressed interest to us in making this type of information available for other providers and suppliers of ambulance services. For example, air ambulance organizations have suggested they are interested in making this information available. We recognize that the

regulation of air ambulances spans multiple federal agencies, and note that section 418 of the FAA Reauthorization Act of 2018 (Pub. L. 115–254, enacted October 5, 2018) requires the Secretary of Transportation, in consultation with the Secretary of HHS, to establish an advisory committee that includes HHS; DOT; insurance regulators; patient and consumer advocacy groups; physicians specializing in emergency, trauma, cardiac, or stroke; various segments of the air ambulance industry; and others. This committee will review options to improve the disclosure of charges and fees for air medical services, better inform consumers of insurance options for those services, and better inform and protect consumers of these services. We welcomed comments on the state of the air ambulance industry and how CMS can work within its statutory authority to ensure that appropriate payments are made to air ambulance organizations serving the Medicare population.

We received 58 public comments on our proposals to establish a ground ambulance data collection system, including 11 public comments on air ambulance payments from air ambulance organizations, air and ground ambulance organizations, an international trade association that represents providers of emergency air medical services and critical care ground medical transport services, an insurance company and a national heart association. The following is a summary of the comments we received and our response.

Comments: Many commenters stated that they appreciate that CMS proposed to establish a data collection system for ground ambulance providers and suppliers, but noted that ground ambulance transportation is only a part of the overall emergency medical services ecosystem. Some commenters described the vital role of air medical services in providing timely critical care responses to high-acuity life-or- death incidents, and stated that air medical service providers and suppliers are the critical link to tertiary care in severe medical emergencies.

Several commenters stated that the current payment rates for air ambulance services are inadequate and that, except for the annual ambulance inflation factor (AIF), CMS has not adjusted the AFS since it was established in 2002. They stated that prior to 2006, CMS had exercised its authority to make periodic adjustments to the AFS based on the actual costs of providing air medical transportation, and that Medicare payments have failed to keep pace with costs of providing air medical services. One commenter stated that ensuring that Medicare beneficiaries continue to have access to air medical transportation when they need it the most should be a priority for the Medicare program, and another commenter suggested that the Medical or Transportation Consumer Price Index (CPI) should be used to update air ambulance payments. Other commenters noted that the Medicare payment rate has an impact on Medicaid payment rates, as well as payment rates from private payors. Commenters described the various factors that are increasing the cost of providing air medical services, particularly in rural areas.

According to several commenters, air ambulance providers and suppliers have access to detailed cost information and are willing to share this information with CMS. Several stated that there is an existing study entitled ''Air Medical Services Cost Study Report'' (March 24, 2017; Xcenda) that provides accurate information on the costs of providing air ambulance services, and that this study could be used to determine appropriate payment for air ambulance providers and suppliers under the Medicare program.

Some commenters encouraged CMS to continue to explore ways to collect the same cost, revenue, and utilization data from air ambulance providers and suppliers that it has proposed to collect from ground ambulance providers and suppliers. Some commenters stated that ground and air ambulance services are increasingly contributing to growing healthcare expenditures and that they appreciate CMS' efforts to better understand the associated services and costs.

Several commenters urged CMS to exercise its existing authority to develop, with stakeholder input, a data collection process that would provide CMS with current cost data that could be used to rebase the AFS. The commenters also stated that this would result in more adequate Medicare payment rates for air ambulance services, and that this would also address inadequate payment from commercial insurers.

Response: We agree that it is essential that Medicare beneficiaries have adequate access to ambulance services, especially in rural areas, and we appreciate the comments regarding the adequacy of the Medicare air ambulance rates and the suggestions regarding updating those rates. We note that section 1834(l)(17) of the Act, which is the authority for establishing a ground ambulance services data collection system, applies only to providers and suppliers of ground ambulance services. Accordingly, we do not have the statutory authority to implement a data collection system for air ambulance services at this time.

3. Research To Inform the Development of a Ground Ambulance Data Collection System

To inform the development of a ground ambulance data collection system, including a representative sampling plan, our contractor developed recommendations regarding the methodology for collecting cost, revenue, utilization and other information from ground ambulance providers and suppliers (also collectively referred to in this final rule as ''ground ambulance organizations'') and a sampling plan consistent with sections 1834(l)(17)(A) and (B) of the Act. Our contractor also developed recommendations for the collection and reporting of data with the least amount of burden possible to ground ambulance organizations. The recommendations took into consideration the following:

- An environmental scan consisting of a review of existing peer-reviewed literature, government and association reports, and targeted web searches. The purpose of the environmental scan was to collect information on costs and revenues of ground ambulance transportation services, identify background information regarding the differences among ground ambulance organizations including state and local requirements that may impact the costs of providing ambulance services, and describe financial challenges facing the ambulance industry. Five previously fielded ambulance cost collection tools were also identified and analyzed and are described below.
- Interviews with ambulance providers and suppliers, billing companies, and other stakeholders to determine all major cost, revenue, and utilization components, and differences in these components across ground ambulance organizations. These discussions provided valuable information on the process for developing a data collection system, including how to best elicit valid responses and limit burden on respondents, as well as the timing of the data collection.
- Analyses of Medicare claims and enrollment data, including all fee-for-service (FFS) Medicare claims with dates of service in 2016, the most recent complete year of claims data for ground ambulance services.

Our contractor also analyzed the following five data collection tools that currently collect or have collected data from ground ambulance organizations:

• The Moran Company Statistical and Financial Data Survey (the ''Moran survey'').[88] In 2012, American Ambulance Association (AAA) commissioned a study with the goal of developing a data collection tool and making recommendations for collecting data to determine the costs of delivering ground ambulance services to Medicare beneficiaries. The result was the Moran survey, which is a two-step data collection method in which all ambulance providers and suppliers first complete a short survey with basic descriptive information on their characteristics, and second, a representative sample of ambulance providers and suppliers report more specific cost information.

• Ground Emergency Medical Transportation (GEMT) Cost Report form and instructions from California's Medicaid program.[89] The GEMT Cost Report form and instructions is used by some states to determine whether ambulance providers and suppliers should receive supplemental payments from state Medicaid programs to cover shortfalls between revenue and costs. This data collection tool is geared toward government entities, as private ambulance providers and suppliers do not qualify for the supplemental payments.

• The Emergency Medical Services Cost Analysis Project (EMSCAP) framework.[90] The National Highway Traffic Safety Administration funded EMSCAP in 2007 to develop a framework for determining the cost for an EMS system at the community level. Subsequently, EMSCAP researchers used this framework to develop a cost workbook and pilot test the tool on three communities representing rural, urban, and suburban areas. EMS services within the three communities included volunteer, paid, and combination EMS agencies, both fire department and third service-based. Third service-based refers to services provided by a local government that include a fire department, police department and a separate EMS, forming an emergency trio.

• A 2012 Government Accountability Office (GAO) ambulance survey.[91] To examine ground ambulance suppliers' costs for transports, in 2012 GAO administered a web-based survey to a random sample of 294 eligible ambulance suppliers. GAO collected data on their 2010 costs, revenues, transports, and organizational characteristics. Although the GAO survey collected data for each domain at the summary level, it also prompted respondents to take into account multiple factors when calculating their summary costs.

• The Rural Ambulance Service Budget Model.[92] This tool was developed by a task force of the Rural EMS and Trauma Technical Assistance Center with funds from the Health Resources and Services Administration (HRSA) in the early 2000s. The purpose was to provide assistance to rural ambulance entities in establishing an annual budget and to calculate the value of services donated by other entities, as well as services donated by the ambulance entity's staff to the community. The tool was last updated in 2010 and has been cited as a resource for rural ground ambulance organizations by state and national government agencies. However, use of the tool is not required by any of these agencies.

As discussed in the proposed rule, our contractor's analysis of these tools revealed that while there was overlap of the broad cost categories collected (for example, labor, vehicles, and facilities costs) via these tools, there were significant differences in the more specific data collected within these broad categories. Overall, there was a large amount of variability regarding whether the tools allowed for detailed accounting of costs and whether the tools used respondent-defined or survey-defined categories for reporting. The five tools also differed in terms of their instructions, format, and design in terms of how a portion of organizations' total costs were allocated to ground ambulance costs, the timeframe for reporting, and the flexibility of reporting.

Based on these activities, our contractor prepared a report entitled, ''Medicare Ground Ambulance Data Collection System—Sampling and Data Collection Instrument Considerations and Recommendations'' (referred to as ''the CAMH[93] report'') which is referenced throughout this final rule. It is available at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html* and provides more detail on the research, findings and recommendations concerning the data collection instrument and sampling.

We received comments on our research, including testing, to inform the data collection system. The following is a summary of the comments we received and our responses.

Comment: While commenters were generally very supportive of the proposed data collection system, several commenters stated that testing is a critical step in the development of any survey and they were disappointed that we did not test the data collection instrument and sampling methodology prior to making our proposals. To address these concerns, the commenters recommended that CMS assess the quality and consistency of submitted data throughout the first year of data reporting, and consider revisions to the data collection instrument either during or after the first year of data collection to address any issues that are identified. They also asked that CMS work with stakeholders to provide any needed clarifications for subsequent collection years and make any adjustments necessary to assure that a statistically appropriate representative sample is obtained. A commenter recommended that CMS not wait for rulemaking cycles to clarify definitions or make other minor changes to the system, and that doing so would slow down the process and make the first years of data less useful. Many commenters urged CMS to provide substantial education to ground ambulance organizations and develop definitions and instruction manuals to ensure that accurate and usable data is obtained from all types of services as quickly as possible.

Response: While the data collection system and instrument was not widely tested prior to making our proposals, we conducted an extensive environmental scan as described above, consulted with as many stakeholders as possible throughout the tight timeframe between when the law was enacted and the statutory deadline for specifying the data collection system. This included meeting with all the major associations representing ground ambulance

[88] The Moran Company (2014). Detailing ''Hybrid Data Collection Method'' for the Ambulance Industry: Beta Test Results of the Statistical & Financial Data Survey & Recommendations, [Online]. Available at *https://s3.amazonaws.com/americanambulance-advocacy/AAA+Final+Report+Detailing+Hybrid+Data+Collection+Method.pdf.*

[89] State of California—Health and Human Services Agency Department of Health Care Services Ground Emergency Medical Transportation (2013). Ground Emergency Medical Transportation Services Cost Report General Instructions for Completing Cost Report Forms, [Online]. Available at *http://www.dhcs.ca.gov/provgovpart/documents/gemt/gemt_cstrptinstr.pdf.*

[90] Lerner, E.B., Nichol, G., Spaite, D.W., Garrison, H.G., & Maio, R.F. (2007). A comprehensive framework for determining the cost of an emergency medical services system. Available at *https://www.mcw.edu/departments/emergency-medicine/research/emergency-medical-services-cost-analysis-project.*

[91] U.S. Government Accountability Office (2012). Survey of Ambulance Services. Available at *https://www.gao.gov/assets/650/649018.pdf.*

[92] Health Resources and Services Administration. The Rural Ambulance Service Budget Model, [Online]. Available at *https://www.ruralcenter.org/resource-library/rural-ambulance-service-budget-model.*

[93] CMS Alliance to Modernize Healthcare.

providers and suppliers, and conducting interviews with randomly selected ground ambulance organizations as described in our contractor's report. Given the extensive effort that has gone into preparing the data collection instrument and sampling plan, as well as the overall positive feedback we received from commenters to the proposed rule, we believe the data collection instrument and sampling plan will achieve the requirements of the statute. We also plan to conduct extensive stakeholder outreach and develop educational materials to help respondents report accurate information, and will make revisions to the data collection instrument and sampling plan as expeditiously as possible to address any issues that are identified.

4. Final Policies for the Data Collection Instrument

a. Format

In the proposed rule, we discussed several options we considered for collecting the data including a survey, a cost report spreadsheet similar to the GEMT, and the Medicare Cost Report (MCR). During interviews with ambulance providers and suppliers, some participants stated that they would prefer that data collection be done through a cost report spreadsheet, rather than a survey, such as the GEMT and other similar data collection tools utilized by state Medicaid programs. They noted that data cost collection spreadsheets such as the GEMT are used in some states where supplemental payments are made to ground ambulance organizations based on costs and revenue reported via a cost reporting template. Although these tools are valuable to the ambulance suppliers that utilize them for Medicaid payment purposes, we noted that only a small number of states make use of these tools for the purpose of providing supplemental payments and that they are generally geared toward government run entities that provide a broad range of emergency medical services and not just ground ambulance services. We stated that for these reasons, we did not believe that these tools could be used by all ground ambulance organizations for Medicare payment purposes without significant revision.

During stakeholder outreach, other ambulance providers and suppliers stated their preference for survey-based reporting such as the Moran survey, because they believe survey reporting is less burdensome and allows more flexibility for reporting. We agreed that survey reporting can be designed to provide greater flexibility of reporting with reduced reporting burden. However, the Moran survey recommended excluding small ground ambulance organizations with limited capacity or those which relied heavily on volunteer services, which we stated would exclude a large percentage of ground ambulance organizations from our sample, would not take into account the unique differences of government run ground ambulance entities, and could not be used by all ground ambulance organizations without significant revisions. Some ambulance organizations that favored using the Moran survey also recommended using cost reporting guidelines that are similar to the CMS requirements for the MCR. In the proposed rule, we stated that although we agree that standardization is important for data analysis, many smaller ground ambulance organizations have stated they would have difficulty complying with complex cost reporting guidelines. We stated that we believed that requiring ground ambulance organizations to complete and submit an MCR for the purpose of the data collection required in section 1834(l)(17) of the Act would be unnecessarily resource intensive and burdensome.

In the proposed rule, we also considered using multiple instruments or staged data collection as recommended in the Moran Report, where we would first collect organizational characteristic data from all ground ambulance organizations, use that information for sampling purposes, and then collect cost and revenue information from a sample of ambulance providers and suppliers. Using this approach, we stated we would need 100 percent participation from all ground ambulance organizations in reporting the organizational characteristic data in order for the data to be used for sampling purposes. We did not propose this approach because we believed multiple data collections would increase respondent burden and may not align with sections 1834(l)(17)(A) and (B) of the Act which requires CMS to collect data from a random sample and prohibits data collection from the same ground ambulance organizations in 2 consecutive years to the extent practicable.

In the proposed rule, we stated that we did not believe that any of the existing or previously used data collection instruments described above would be sufficient to adequately capture the data required by section 1834(l) of the Act. Therefore, we proposed to collect ground ambulance organization data using a survey that we developed specifically for this purpose, referred to as the data collection instrument, via a secure web-based system. We stated that we believed that the data collection instrument should be usable by all ground ambulance organizations, regardless of their size, scope of operations and services offered, and structure and proposed that the data collection instrument include screening questions and skip patterns that direct ground ambulance organizations to only view and respond to questions that apply to their specific type of organization. We stated that we also believed that the data collection instrument we proposed is easier to navigate and less time consuming to complete than a cost report spreadsheet. We also stated that the secure web-based survey would be available before the start of the first data reporting period to allow time for users to register, receive their secure login information, and receive training from CMS on how to use the system. Finally, we proposed to codify these policies at § 414.626.

We received comments on the format of the data collection instrument. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that they support our proposal to collect ground ambulance data using a survey developed specifically for this purpose and not use existing GEMT workbooks or Medicaid cost reports because they do not believe that either would provide the necessary information for CMS and MedPAC to use when addressing the questions that Congress set forth in the statute. They also expressed support for our approach to the development of a web-enabled data collection system and the principles that guided the development of the data collection instrument. In particular, they noted our goal of developing a system that will balance respondent burden against the need to collect the data required by the statute, provide flexibility to collect data from diverse ambulance organizations, and enable the calculation of per-transport costs for comparison to Medicare payment rates. They encouraged us to collect the data in a manner that allows for as much analysis as possible, such as the comparison of per- transport costs across subgroups of ambulance organizations, and analyses estimating the marginal cost of a particular type of transport. These commenters stated that they believe the proposed data collection system and draft Medicare ground ambulance data collection instrument provide a solid foundation for future evaluation.

Some commenters stated that while they would have preferred a spreadsheet

for the data collection instrument, they agree that the proposed web-based survey with skip logic and other embedded tools to help ground ambulance organizations navigate the data collection instrument will be helpful. They asked that CMS consider ways that web-based tools can leverage the technology to provide additional clarity around the data submission. For example, they stated that it may be useful to include standardized definitions or address common questions by incorporating links to specific questions to the terms/answers and to have definitions or allocation rules ''pop-up'' on the screen when a user starts a new question. One commenter requested that the data collection system allow enough time for the respondent to complete the information, to save partially completed data, and easily come back to where they left off to edit or continue entering the data. Commenters stated that they would welcome the chance to walk through the data collection system, as well as the data collection instrument once it is coded and share ideas about how the web-based nature of it can be refined. They would also like to work with CMS to find ways that may allow for easier data entry, including auto-population of certain fields and an application programming interface (API) import method from commonly used accounting software.

While nearly all commenters expressed support for the proposed format of the data collection instrument, some commenters were concerned that due to the complexity of the data collection instrument, the response rate will be low and that the submitted data may be inaccurate, particularly for smaller ground ambulance organizations. One commenter recommended that low-volume ambulance organizations (for example, those providing 600 or fewer all-payer ground transports per year) should only be required to complete a much shorter version of the proposed data collection instrument in order to increase the response rate. This commenter suggested that for low-volume ambulance organizations, only the minimum information needed to calculate the organization's cost per transport, such as the organization's total annual budget, total number and type of transports regardless of payer, average number of miles per transport, type of organization, non-profit vs. for-profit status, use of shared space, and percent of labor hours from volunteers, should be collected.

Response: We thank the commenters for the overwhelming support of the proposed format of the data collection instrument and will implement many of the suggestions commenters provided to ensure the data collection system is user friendly and provides as many avenues for analysis as possible.

We understand the concern that upon first glance, the data collection instrument may appear complex, as well as the concern that it may suffer from a low response rate. However, we expect that ambulance organizations will find that the use of screening questions and skip patterns that direct them to only view and respond to questions that apply to their specific type of organization will be easier to navigate and less time consuming to complete than a cost report spreadsheet. We believe that the data collection instrument will be usable by all ground ambulance organizations regardless of their size or other characteristics, and do not believe it is necessary or beneficial to have a limited data collection instrument for low-volume ambulance organizations to complete. Our belief is that all ground ambulance organizations that are chosen to participate in the sample will work with CMS and their ambulance associations to receive the assistance they need to report the data required, not just because they will receive a 10 percent payment reduction for failure to report the data, but also because they believe their data is important so that those analyzing the data can accurately assess whether or not Medicare payment rates are adequate. We specifically designed the data collection instrument to leave as many doors open as possible for data analysis while also considering the burden associated with every question.

Comment: Some commenters expressed concern that information on key organizational characteristics (such as organization type and use of volunteer labor) are being collected as part of this data collection effort, rather than in a separate data collection process that would occur before the collection of cost and revenue data. They stated this two-stage approach to data collection is needed to stratify the sample and ensure a representative sample.

Response: We recognize the desire that many commenters shared to have all of the organizational characteristic data prior to selecting samples to ensure that CMS has what commenters believe would be a complete set of data to use to stratify the sample. As stated in the proposed rule, we believe that Medicare claims and enrollment data provide CMS with enough data to appropriately stratify the sample. We also continue to believe that multiple data collections would increase respondent burden and that the commenters' suggestion to collect data from all ground ambulance organizations in the first data collection and then select a random sample to collect data from some ground ambulance organizations in that same year or the year after may not align with sections 1834(l)(17)(B) of the Act, which requires CMS to collect data from a random sample and prohibits data collection from the same ground ambulance organizations in 2 consecutive years, to the extent practicable. Furthermore, we believe that collecting data on organizational characteristics as part of one data collection effort will enable skip patterns within the survey to limit the number of questions organizations with certain characteristics will need to answer.

After consideration of the comments, we are finalizing our proposal to collect ground ambulance organization data using a single survey-based data collection instrument delivered via a secure web-based system. We made a few technical changes to our proposals to codify these policies at § 414.626 including adding a definition for Medicare Ground Ambulance Data Collection Instrument. We are finalizing our proposals to codify these policies at § 414.626.

b. Scope of Cost, Revenue, and Utilization Data

Section 1834(l)(17)(A) of the Act requires CMS to develop a data collection system to collect data related to cost, revenue, utilization, and other information determined appropriate by the Secretary for ground ambulance organizations. Section 1834(1)(17)(A)(i) of the Act further specifies that the information collected through the system should be sufficient to evaluate the extent to which reported costs relate to payment rates.

In the proposed rule we stated that we considered several options regarding the scope of collecting data on ground ambulance cost, revenue, and utilization. One option was to require ground ambulance organizations to report on their: (1) Total costs related to ground ambulance services; (2) total revenue from ground ambulance services; and (3) total ground ambulance service utilization. We stated that this approach considers all ground ambulance costs, revenue, and utilization, regardless of whether the service was billable to Medicare or related to a Medicare beneficiary and that the advantage of this approach is that ground ambulance organizations already track information at their

organizational level on total costs, revenue, and utilization for their own internal budgeting and planning. We stated that this method was also used to calculate an organization-level average cost per transport in two previous studies described below:

In a 2012 study entitled, ''Ambulance Providers: Costs and Medicare Margins Varied Widely; Transports of Beneficiaries has Increased'',[94] the GAO performed an analysis to assess how Medicare payments, including the temporary add-on payments, compared to costs reported using a survey. The GAO collected information via a survey on organizations' total costs, including operating and capital costs, without restriction to costs associated with Medicare transports or costs incurred in responding to calls for service from Medicare beneficiaries. GAO then divided reported total costs by the reported number of transports (regardless of whether Medicare paid for the transport) to calculate an average cost per transport for each organization, and reported summary statistics across these averages, including a median cost per transport of $429. However, to simplify data collection and analysis, the analysis was limited to ambulance suppliers that did not share operational costs with a fire department, hospital, or other entity. GAO stated that its calculations assumed that this average cost per transport was constant for all of an organization's transports regardless of whether or not the patient transported was a Medicare beneficiary. This approach implicitly loads the costs associated with activities that did not result in a transport, such as responses by a ground ambulance where the patient could not be located, refused transport, or was treated on the scene, into the estimated cost per transport.

The second study, ''Report to Congress Evaluation of Hospitals' Ambulance Data on Medicare Cost Reports and Feasibility of Obtaining Cost Data from All Ambulance Providers and Suppliers,'' [95] was conducted by HHS as required under the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L 112–240, enacted January 2, 2013). This report used data from Medicare cost reports as its data source, rather than a survey, and included only ambulance providers, rather than ambulance providers and suppliers. It described substantially higher costs per transports for ambulance providers compared to the estimate from GAO, with a median of approximately $1,750 per transport. It did not compare reported total costs to Medicare revenue tallied in claims data with and without the temporary add-on payments. Neither the GAO nor the HHS report compared costs and AFS payment rates for specific Healthcare Common Procedure Coding System (HCPCS) codes because the available cost data in both studies did not support that level of analysis.

Another option we discussed in the proposed rule was considering only those costs that are relevant to ground ambulance services furnished to Medicare beneficiaries. We stated that collecting costs associated with specific services (such as Medicare transports) and excluding other services (such as Medicaid transports or responses that did not result in transport) would require either a much more intensive and costly data collection approach (such as time and motion studies) or assumptions on which portions of total costs were related to the specific activity. We also stated that we believed this approach would be overly burdensome and complex for ground ambulance organizations, especially those who provide other services in addition to ground ambulance services.

A third option we considered for the proposed rule was to only consider those costs that are related to the specific ground ambulance transport services that are paid under the AFS. We stated that this would require ground ambulance organizations to report costs, revenue, and utilization related to specific levels of services reported with HCPCS codes, but not costs, revenue, and utilization for other services such as responses that did not result in a transport (which is not covered under the AFS). In the proposed rule we stated that we believe this option would be overly burdensome and complex.

We stated that in discussions with ambulance providers and suppliers, we were informed that ground ambulance organizations most often track organization-level total costs, revenue, and utilization across all activities and services furnished to all patients. We were told that most would find it difficult to report costs, revenue, and utilization associated with services furnished exclusively to Medicare beneficiaries or associated with Medicare services covered under the AFS.

Therefore, we proposed the first option, which would require ground ambulance organizations to report on their: (1) Total costs related to ground ambulance services; (2) total revenue from ground ambulance services; and (3) total ground ambulance service utilization. We stated that this approach considers all ground ambulance costs, revenue, and utilization, regardless of whether the service was billable to Medicare or related to a Medicare beneficiary to collect total cost, total revenue, and total utilization data.

Although we proposed to collect a ground ambulance organization's total costs and total revenues, we stated we were aware that many ground ambulance organizations share operational costs with fire departments, other public service organizations, air ambulance services, hospitals, and other entities. We stated that for these organizations, only a portion of certain capital and operational costs contribute to total ground ambulance costs, and only a portion of revenue is from ground ambulance services. We also stated we were aware that some ground ambulance suppliers deploy emergency medical technicians (EMTs) in fire trucks, which will make it difficult to determine whether the fire truck costs should be factored into the total ground ambulance costs, and if so, how that will be calculated.

In the proposed rule, we stated that one option to address these challenges is to limit data collection to ground ambulance organizations that do not share operational costs with fire departments, hospitals, or other entities, as GAO did for their 2012 report. We stated that we did not believe this approach meets the requirement in section 1834(l)(17)(B)(ii) of the Act for a representative sample because many ambulance suppliers and all ambulance providers share operational costs with fire, police, health care delivery or other activities. We also considered including providers' and suppliers' total costs and revenues across all activities and stated that while this would simplify cost and revenue data reporting, the resulting data would not be limited to ground ambulance activities, and therefore, would result in biased estimates of ground ambulance costs or require significant assumptions to estimate ground ambulance costs alone.

To more accurately define total costs and total revenues related to ground ambulance services for those ground ambulance organizations that provide other services in addition to ground ambulance services, we proposed an approach where the data collection instrument instructions would separately address three further refined proposed categories of total ground ambulance costs and revenues:

[94] This report is available at *https://www.gao.gov/assets/650/649018.pdf.*

[95] This report is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf.*

• *Cost and revenue components completely unrelated to ground ambulance services.* In the proposed rule, we stated these costs and revenues would be unrelated to this data collection and not reported. We gave examples that included administrative staff without ground ambulance responsibilities, health care delivery outside of ground ambulance, community paramedicine, community education and outreach, and fire and police public safety response.

• *Cost and revenue components partially related to ground ambulance services.* We stated these costs and revenue would be reported in full, but respondents would report additional information that could be used to allocate a portion of the costs to ground ambulance services. We stated that depending on how the data would be utilized, certain costs could be included or excluded from an analysis after data are collected. We provided examples to include EMTs who are also firefighters and facilities with both ground ambulance and fire department functions. (We stated that we considered an alternative where respondents would allocate costs and report only costs associated with ground ambulance services but believed that would pose an additional burden on the respondent to calculate allocated amounts, and would result in an allocation process that is less transparent and standardized).

• *Cost and revenue components entirely related to ground ambulance services.* We stated that these costs are reported in full. We gave an example to include EMTs with only ground ambulance responsibilities and ground ambulance vehicles.

In the proposed rule, we stated that we believe that this approach will enable us to collect the data necessary to evaluate the adequacy of payments for ground ambulance services, the utilization of capital equipment and ambulance capacity, and the geographic variation in the cost of furnishing such services. We stated that the data could be analyzed in the same manner as the data in the GAO report, for example, calculating an average per-transport cost for each organization and calculating Medicare margins with and without add-on payments, or could provide the basis for other analyses to link reported costs to AFS rates. We stated that an analysis could use reported total costs and information on the volume of transports by levels of services to estimate a cost for each HCPCS code reported for the AFS, or regression-based approaches to estimate the marginal cost of furnishing each HCPCS code on the AFS. We stated that we believed that under our approach, the collected data will be available to estimate total costs and revenue relevant to ground ambulance services.

We received comments on scope of cost, revenue, and utilization data.

Comment: Many commenters stated that they support CMS' approach to collect data on total costs related to ground ambulance services, total revenue from ground ambulance services, and total ground ambulance service utilization. They stated that they support this approach because it will provide the most accurate and complete view of ground ambulance costs, revenue, and utilization.

Commenters also expressed support of CMS' proposal to collect data in such a way that will allow the allocation of a share of organizations' total costs to ground ambulance services in cases where an organization also provides other services or activities. Commenters stated that separating ground ambulance costs from non-ground ambulance costs is essential for the data collection system to comply with the intent of the Congress when it established the new program. They also stated that they agree that the data collection instrument should provide clear instructions to separately address these costs while in many cases allowing them to be reported and that the clear definition of these terms will be critically important to ensure the consistent application of these categories.

Finally, one commenter expressed concern that several categories of ''hidden'' or ''opportunity'' costs were not captured in the data collection instrument. These include, but are not limited to: volunteers using their own cars to respond to calls; the time/money volunteers lose in responding to calls, and position vacancies that organizations cannot fill or needed capital equipment or buildings that they cannot purchase due budget constraints. The commenter noted these ''hidden costs'' artificially lower the cost of running an ambulance service for some organizations.

Response: We agree that it is critical to collect data in such a way that ground ambulance costs can be separated from an organization's total costs in cases where an organization performs ground ambulance and other activities. The approach that we proposed would collect information in such a way that analysts (rather than the respondent) would be able to allocate many costs to ground ambulance services.

We also do not agree with the commenter who suggested that we collect information on what they described as ''hidden'' costs. The statute requires us to collect information on actual costs, not on costs that would have occurred under certain circumstances. We believe that the proposed data collection instrument will provide the necessary data required by the statute, and collecting information on other costs or potential costs would be out of scope for this data collection.

After consideration of the comments, we are finalizing our proposals to collect data on total costs related to ground ambulance services, total revenue from ground ambulance services, and total ground ambulance service utilization. We are also finalizing our proposals regarding allocation of a share of organizations' total costs and revenues unrelated to, partially related to, and entirely related to ground ambulance services.

c. Final Data Collection Elements

In the proposed rule, we shared the proposed data collection instrument on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.* We provided an overview of the elements of the data collection instrument we proposed in Table 37, including information on costs, revenues, utilization (which we define for the purposes of the data collection instrument as service volume and service mix), as well as the characteristics of ground ambulance organizations.

In the proposed rule we stated that to help structure the data collection instrument, we organized costs by category (for example, labor, vehicles, and facilities), which we stated was the approach used in the GEMT and the AAA/Moran survey.

TABLE 37: Components for the Data Collection Instrument

Component (Data Collection Instrument Section)	Broad Description
Ground ambulance organization characteristics (2-4)	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other characteristics; broad questions about offered services to serve as screening questions.
Utilization: Ground ambulance service volume and service mix (5 and 6)	Number of responses and transports, level of services reported by HCPCS code.
Costs (7-12)	Information on all costs partially or entirely related to ground ambulance services.
• Staffing and Labor Costs (7)	Number and costs associated with EMTs administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities Costs (8)	Number of facilities; rent and mortgage payments, insurance, maintenance, and utility costs.
• Vehicle Costs (9)	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual depreciation; total fuel, maintenance, and insurance costs.
• Equipment & Supply Costs (10)	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other Costs (11)	All other costs not reported elsewhere.
• Total Cost (12)	Total costs for the ground ambulance organization included as a way to cross-check costs reported in the data collection instrument.
Revenue (13)	Revenue from health insurers (including Medicare); revenue from all other sources including communities served.

(1) Collecting Data on Ground Ambulance Provider and Supplier Characteristics

We are required to collect information regarding the geographic location of ground ambulance organizations to meet the requirement at section 1834(l)(17)(A)(iii) of the Act that the collected data include information on services furnished in different geographic locations, including rural areas and low population density areas. In the proposed rule, we stated that we recognized that there are differences between and among ground ambulance organizations on several key characteristics, including geographic location; ownership (for-profit or non-profit, government or non-government, etc.); service volume, organization type (including whether costs are shared with fire or police response or health care delivery operations); EMS responsibilities; and staffing models. We stated that our research indicated that:

- There are differences in costs per transport by ground ambulance organizations with a different ownership status;
- EMS level of service and staffing models often have an important impact on costs, with higher EMS levels of service (for example, quicker response times) and static staffing models (that is, mainatining a constant response capability 24 hours a day, 7 days a week, 365 days a year) involving higher fixed costs; and
- Utilization varies significantly across ambulance providers and suppliers of different characteristics.

Due to this variation in characteristics and the effect it has on costs and revenues, we stated that we believed it is important for ground ambulance organizations to report additional characterictics to adequately analyze the differences in costs and revenue among different types of ambulance providers and suppliers. We also stated that we believed collecting this information directly through the data collection instrument will improve data quality with minimal burden on the respondents because the data collection instrument was designed to tailor later sections and questions based on respondents' characteristics through programmed ''skip patterns''. We stated we considered relying exclusively on the Medicare enrollment form CMS 855A for ground ambulance providers or CMS 855B for ground ambulance suppliers to capture this information, but believed that data accuracy would be more robust if reported directly by respondents for the specific purpose of this data collection.

We proposed to collect information on ownership and organization type through a sequence of questions in Section 2 of the data collection instrument. We stated that some of the questions in this section were adapted in part from prior surveys (such as the GAO and Moran surveys) with changes as necessary to fit scenarios reported during interviews with ground ambulance organizations. The first question related to organizational characteristics, question 6, asked about the organizations' ownership status and aligned closely with a similar question on the Medicare enrollment form CMS 855B for ambulance suppliers. Question 7 asked whether the respondent's organization used any volunteer labor. While this question could have been asked later in the data collection instrument around the collection of labor data, we stated we opted to include it here because many ground ambulance organizations informed CMS that they view the use of volunteer labor as a defining organizational characteristic, on par with ownership status, and that a volunteer labor question was expected by respondents at this early point in the data collection instrument. Question 8 asked

respondents to select a category that best describes their ambulance organization. We stated that the response options for this item are mutually exclusive and align with the ambulance provider and supplier taxonomy described in the CAMH report. The next two questions, 9 and 10, more directly asked whether the respondent has shared operational costs with an entity of another type, including a fire department, hospital, or other entity. We stated that we proposed these questions in addition to the organization type question to account for situations where a respondent might primarily identify as an organization of one type (with implications for shared operational costs) but then might have shared operational costs with another entity type. We stated that responses to questions 9 and 10 play an important role in skip logic later in the data collection instrument regarding questions and response options relevant only to ground ambulance organizations with shared operational costs with an entity of another type.

We stated that other questions regarding organizational characteristics are necessary to tailor later parts of the data collection instrument to the respondent. These included questions in Section 2 of the data collection instrument on whether the respondent's ambulance organization:

- Is part of a broader corporation or other entity billing under multiple National Provider Identifiers (NPIs) (question 2).
- Routinely responds to emergency calls for service (question 11).
- Operates land, water, and air ambulances (questions 12–14).
- Has a staffing model that is static (that is, consistent staffing over the course of a day/week) or dynamic (that is, staffing varies over the course of a day/week) or combined deployment (certain times of the day have a fixed number of units, and other times are dynamic depending on need) (question 15).
- Provides continuous (also known as ''24/7/365'') emergency services) (question 16).
- Provides paramedic or other emergency response staff to meet ambulances from other organizations in the course of a response (questions 17 and 18).

In our interviews with ambulance providers and suppliers, some participants indicated that their staffing model is an organizational characteristic that would likely be associated with costs per transport and that organizations that need to maintain fixed staffing levels over time (for example, to maintain an emergency response capability to serve a community) would likely have higher costs than those that do not.

Section 1834(l)(17)(A)(iii) of the Act requires collecting data from ambulance providers and suppliers in different geographic locations, including rural areas and low population density areas. In the proposed rule, we stated that the area served by ambulance organizations is an important characteristic and we proposed to collect information on the geographic area served by each ambulance organization in Section 3 of the data collection instrument.

In the proposed rule, we stated that many ground ambulance organizations have a primary service area in which they are responsible for a certain type of service (for example, ALS–1 emergency response within the borders of a county, town, or other municipality) and may have secondary services areas for a variety reasons, such as providing mutual or auto aid, or providing a different service in a secondary area (for example, non-emergency transports state-wide). For the proposed rule, we considered several alternatives to collect information on service area. One option was to utilize Medicare claims data, but we stated that this would limit the information to Medicare billed transports only and would also not differentiate between primary and other service areas. Another option was to allow respondents to write in a description of their primary and other service areas, but we stated this would require converting written responses to a format that can be used for analysis. A third option was for respondents to report the ZIP codes that constitute their primary and other service area. We stated this approach aligns with the Medicare enrollment process requirement to submit ZIP codes where the ground ambulance organization operates and that it would also collect ZIP code-based information on service area that can be easily linked to the ZIP Code to Carrier Locality file [96] that lists each ZIP code and its designation as urban; rural; or super-rural. We stated that this file is used by the MACs to determine if the temporary add-on payments should apply to a transport under the AFS. We also stated the main limitation of this approach is that ZIP codes would not always align to service areas, because ZIP codes routinely cross town, county, and other boundaries that are likely relevant for defining ground ambulance organizations' service areas.

We proposed to require ground ambulance organizations that are selected during sampling to identify their primary service area by either: (1) Providing a list of ZIP codes that constitute their primary service area; or (2) selecting a primary service area using pre-populated drop-down menus at the county and municipality level in question 1, Section 3 of the data collection instrument. We also proposed to require respondents to specify whether they have a ''secondary'' service area, which we stated are areas where services are regularly provided under mutual aid, auto-aid, or other agreements in Section 3, question 4 of the data collection instrument and if so, to identify the secondary service area using ZIP codes or other regions as described above for the primary service area (Section 3, question 5). We stated that mutual aid agreements are joint agreements with neighboring areas in which they can ask each other for assistance and that auto-aid arrangements allow a central dispatch to send the closest ambulance to the scene. We did not propose to collect information on areas served only in exceptional circumstances, such as areas rarely served under mutual or auto-aid agreements or deployments in response to natural disasters or mass casualty events because we stated we believe reporting on rarely-served areas will involve significant additional burden and will add to complexity of the data collection instrument without generating data that will be useful for analysis.

In the proposed rule, we stated that the proposed approach distinguishes between primary and secondary service areas and will allow subsequent questions on the balance of transports in a respondent's primary versus secondary service area and whether average trip time and response times are substantively longer in the secondary versus primary service area. We stated that we believed this approach results in data that can be easily analyzed and eliminates the need to ask certain other questions (such as the population and square mileage of the respondent's service area) because this information can be inferred using the reported geographic service area boundaries.

We proposed to ask the following questions in Sections 3 and 4 of the data collection instrument, service area and subsequent emergency response time, because the responses to these questions are closely related to the area served by the organization:

[96] Available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html.*

• Whether the respondent is the primary emergency ambulance organization for at least one type of service in their primary service area (Section 3, question 2).
• Average trip time in primary and secondary service areas (Section 3, questions 3 and 6).
• Average response time (for organizations responding to emergency calls for service) for primary and secondary service areas (Section 4, questions 1–2).
• Whether the organization is required or incentivized to meet response time targets by contract or other arrangement (for organizations responding to emergency calls for service) (Section 4, question 3).

In the proposed rule, we stated that average trip and response time are necessary to understand how geographic distance between the ground ambulance organization's facilities and patients affects costs. In interviews, ground ambulance organizations recommended the collection of average trip time in addition to mileage because some rural and remote areas may have relatively long average trip times even though mileage may be more modest due to terrain, the quality of roads, and other factors. We stated that we believed that collecting information on average response time would allow the analysis of whether communities with different response time expectations and targets have systematically different costs.

We received comments on collecting data on ground ambulance provider and supplier characteristics. The following is a summary of the comments we received and our responses.

Comments: Many commenters stated that they are pleased that CMS has recognized the importance of taking into account organizational characteristics in designing the data collection instrument. They stated that even though the organizational characteristics in Section 2 of the data collection instrument differ from those initially recommended by the AAA based on its work with the Moran Company, they believe that in its totality the data collection instrument covers the key organizational characteristics that policy-makers will need to use to accurately determine the cost of providing ground ambulance services. Commenters made several specific recommendations. One commenter recommended that CMS add questions asking whether the respondent has sole source contracts or local jurisdictional requirements and suggested that we add categorical response options (specifically, less than and greater than 20 percent) to the existing question on the use volunteer labor because these characteristics may be systematically related to reported costs and revenue.

Commenters also asked CMS to consider several specific clarifying changes to the data collection instrument including: (1) Clarifying how respondents should respond to question 1 in Section 2 if they have multiple service types under the same NPI; (2) defining NPI; (3) distinguishing between response options for independent/proprietary organization types; (4) specifying which organization name should be reported; (5) defining the term ''public/private partnership;'' (6) adding an ''other'' organization type; (7) clarifying the term 'volunteer' and which volunteer personnel are in-scope when reporting volunteer labor; and (8) clarifying how to classify 501(c)(4) organizations.

Many commenters requested that because the questions in Section 4, emergency response time, are similar to those in Section 3 of the data collection instrument, they would like CMS to provide the same clarification to these questions that they highlighted for Section 3 of the data collection instrument.

One commenter requested clarification on whether the average trip time is calculated across all calls or just specific types such as emergency, scheduled, etc. One commenter recommended that average response time be defined as starting when the call for service is answered to when the first EMS unit arrives on location. The commenter stated this definition is best because it measures response times as experienced by the public/patient. One commenter requested clarification on Section 4, Question 3 which asks whether organizations are penalized for exceeding response time targets, if their local area imposes these standards. The commenter requested clarification on whether any performance penalties should be included in the answer to this question or only response time penalties.

Several commenters also recommended asking ground ambulance organizations to provide 90th percentile response time rather than average response time. They believe 90th percentile response time is a more accurate indicator of ambulance services capabilities and quality. They stated that average time has too wide a range for error, since roughly half of responses are quicker/slower than average. They further stated that using average response time also tends to flatten the data, which means that the fastest and slowest organizations do not stand out as much.

Response: We appreciate commenters' points that much of the information collected via the data collection instrument will be useful in describing variation across ground ambulance organizations. Many of the specific characteristics that commenters suggested adding to the initial section of the data collection instrument are already included in the survey. For example, Section 3 of the proposed data collection instrument asks if the organization is the only EMS provider in most or all of their service area, Section 4 asks about response time targets, and Section 7 asks for detailed information related to volunteer labor. We added screening questions to the initial section of the data collection instrument only when they were necessary to inform skip patterns, and reserved asking other questions until later sections. The information collected via the survey can be used to conduct analyses for various subgroups of organizations, for example those that are and are not the only EMS provider in part or all of their service area.

We thank commenters for pointing out several opportunities to clarify the instructions and items in the proposed data collection instrument. We believe that based on the wording of question 1, Section 2, organizations with more than one service line under the same NPI (such as both air and ground ambulance) should answer ''yes'' to question 1 in Section 2. We agree that the term national provider identifier should be defined at its first use in the data collection instrument. When distinguishing between different types of proprietary/independent ground ambulance organizations, we intended option (e) to reflect primarily EMS responsibilities and option (f) to reflect primary responsibilities that are non-emergency. For the legal name, we are requesting that organizations use their legal name, which should match the name used on their Medicare enrollment form 855B in most cases. For this reason, we encourage all ambulance organizations to confirm that their information is up-to-date in the Medicare enrollment database, the Provider Enrollment Chain and Ownership System (PECOS). A public/private partnership is a formal contractual arrangement between a government and an entity chartered for the express purpose of providing the service. We believe that the response options for the ownership type item (question 6 in Section 2) are comprehensive and no additional ''other'' option is necessary. The volunteer labor question refers to any

volunteers, including non-medical personnel. Any staff member who is paid could not be counted twice, once as a paid staff member and once as a non-paid staff member or volunteer. So in the example of a paid administrator who serves as a volunteer responder, they should be counted in the administrator category since that is the category in which they are paid. Volunteers may receive some forms of compensation but are not considered full or part time employees if they are not paid a minimum wage in return for full or part-time labor. Finally, 501(c)(4) organizations are considered to be for-profit organizations.

We agree that most ground ambulance organizations that respond to emergency calls for service already track response times and that different organizations may use different methodologies for tracking. We also agree that it is important to define the term ''average response time'' to ensure respondents are reporting times measured in a consistent way but we are concerned that specifying one definition or another may result in additional burden for organizations that currently track response time using another definition. We believe that several summary statistics would be useful for analysis, including an estimate of central tendency (like the mean) and an estimate focusing more on outliers (like the 90th percentile). We are also clarifying that response time target penalties do not include performance or any other type of penalties.

As a result of these comments, we will change two of the options in Question 8 to (e) Independent/proprietary organization primarily providing EMS services and (f) Independent/proprietary organization providing non-emergency services. We will also add information on the use of volunteers to clarify that it refers to all volunteer staff, not only response personnel. We will add the text ''that best fits your organization'' to Section 2, question 6, and we will define NPI on the first use of that acronym. We will also add new items on whether or not the organization uses the response time definition in the data collection instrument or another definition, new instructions to clarify that respondents should report response times as they currently measure them, and a new item for the 90th percentile response time. We will revise the data collection instrument to add an initial yes/no question asking whether the organization measures response time specifically as the time from when the call for service is answered to when the first EMS unit arrives on the scene. If the respondent answers yes, we would then ask for response time summary statistics. If the respondent answers no, we would ask them to specify what definition they use.

Comment: Many commenters were pleased that the proposed data collection instrument includes questions on their service area because of the impact of the service area on their costs. They described that in some rural areas, ambulance organizations may have to commit vehicles for several hours for a single response if their service areas cover hundreds of miles. In urban areas, an ambulance organization may face a similar challenge of having a vehicle committed to a single response as it navigates traffic congestion and overcrowded emergency rooms. Commenters were also appreciative that we proposed using ZIP code level data, because as the census data changes, so do the ZIP codes designated as urban, rural, and super-rural. They stated that this information is essential to understand the costs of ambulance organizations providing services in these areas, especially to assess the add-ons and adequacy of current ambulance fee schedule rates. These commenters stated that they appreciate the data elements related to average trip time since having standardized assessment of these elements is also important. They stated that while they had divided the average duration of a transport into three categories, they support the more detailed division in the proposed data collection instrument.

One commenter sought clarification on what CMS means by ''primary service area'' and ''secondary service area''. They inferred that the intent of these distinctions is to allow the end users of the data to be able to allocate the costs appropriately as related to urban, rural, or super-rural areas by proportioning the costs of respondents based on where they provide the most services. They stated that they believe that this approach makes sense as a way to parse out the complexities that an ambulance organization might provide services in more than one geographic designated (for example, urban, rural, super-rural) and that using the ZIP codes rather than the current Medicare definitions of urban, rural, and super-rural will provide consistency in reporting, as the 2020 Census may shift the CMS definitions again. The commenter suggested that, if this assumption is in fact correct, that CMS define the term ''primary service area'' as the area where more than half of its services are provided. The same commenter asked that CMS provide a standard definition to what it means by ''the primary emergency service.'' They stated that while many ambulance organizations will likely know whether they are the only provider of emergency services in an area or not, they may not know the volume of services provided by other organizations if there are others providing these services. They also stated that it could also be helpful to know whether CMS will audit the answers to this question and what will be done with the respondents' data if more than one ambulance organization answers that it is the primary emergency ambulance provider for the same set of ZIP codes. Another commenter requested clarification on whether the secondary service area could include the whole state, or when an organization handles a transfer of a patient to higher level care for another organization.

Response: We thank the commenters for these detailed questions and appreciate the opportunity to provide additional clarification. Each ambulance organization will determine what it considers to be its primary service area, usually based on whether it has primary EMS or responsibilities within a specific jurisdiction or if it has contractual or other arrangements to provide a certain level of service with a particular region (as opposed to an area where it renders aid to other ambulance organizations). We expect that in most cases, well over 50 percent of an organization's transports will occur in the primary service area. Given the lack of information about ambulance organization service areas, we believe it will be useful to collect respondents' subjective assessment of their own primary and secondary service areas, and do not believe that a specific threshold would be relevant for all respondents. For example, there are likely cases where an organization's primary service area by contract accounts for half or less than half of its paid transports if it serves an area with high levels of mutual or auto-aid agreements. While there are other approaches to collect more detailed information on service areas and the arrangements (both formal and informal), responsibilities, levels of service offered, and service volume in different parts of an organization's service area, we believe that the burden involved in collecting this more detailed information would be considerable. Commenters highlighted several examples of cases where it might be difficult to identify whether they have a secondary service area. If an organization operates an emergency service for one jurisdiction but then

operates a non-emergency service in the rest of the state, both may be considered primary since the ground ambulance organization has the primary responsibility for serving both areas. Also, we would not expect that all ground ambulance organizations will have a secondary service area.

We also do not agree with the suggestion to describe primary service areas as those with only one emergency ambulance provider because that would exclude organizations that are the primary emergency ambulance provider in areas where other organizations respond to calls through mutual or auto-aid arrangements on an occasional, but perhaps not an exceptional basis. We understand that ambulance organizations vary in how they define their service areas, and we expect that ground ambulance organizations will report their service area information accurately. We believe the existing question provides us with the detail we need to understand the service area of the responding ground ambulance organization.

After consideration of the comments, we clarified that responses to questions related to the primary and secondary service area should be based on the respondents' best judgment regarding the definition of their organization's primary service area and, if applicable, secondary service area. We further clarified the primary and secondary service area definitions through the new examples in the data collection instrument instructions and making additional edits pertaining to the service area.

Comment: Several commenters suggested adding a question to Section 3 of the data collection instrument that would ask if the ground ambulance organizations uses EMS employees from another agency, such as a fire department or law enforcement agency, either to provide initial patient care/assessment or continue providing patient care during transportation to a hospital or other destination. If the respondent answers no, they would skip to Section 4. If the respondent answered yes, they would be asked the percentage of patient transports that are EMS employees from another response agencies providing initial patient care/assessment or continuing to provide patient care during transportation, and if the ground ambulance organization reimburses this non-transporting agency for the patient care/assessment services they provide.

Commenters stated that they believe it would be beneficial for CMS to gain an understanding of how frequently ground ambulance agencies rely upon a fire department or law enforcement agency for additional EMS personnel to provide patient care. They stated that while they understand that we are focused mostly on obtaining data related to individual patient transportation, they believe it is important to consider the entire EMS response system because that is key to evaluating the efficiency and effectiveness of ambulance organizations that rely upon a third-party agencies (such as a fire department or law enforcement agency) to meet their response-time goals.

These same commenters also asked that CMS include a question in Section 4 of the data collection instrument that asks if a ground ambulance organization responds to calls for service in conjunction with a non-transporting EMS agency, such as a fire department or law enforcement agency. If the respondent answers no, they would skip to Section 5 of the data collection instrument. If the respondent answers yes, they would then be asked for additional information including: The percentage of responses in which a non-transporting agency responds initially to the patient; the percentage of transports where an initial responding EMS provider from another agency continue providing patient care during transport to a destination; if they have a formal agreement with the non-transporting agency to provide these services; and if they reimburse the non-transporting agency for these services. Commenters also stated that often ground ambulance organizations may rely upon a non-transporting fire department or law enforcement agency for the initial response to a call for service in order to ''stop the clock'' and that they believe CMS should include this set of questions to determine how often transporting agencies rely upon a non-transporting agency for initial response and whether the transporting agency is reimbursing the non-transporting fire department or law enforcement agency for this critical response role. Other commenters also suggested that the survey needs to better capture these situations where non-transporting agencies also respond.

Response: The commenters raise an important issue that medical care provided to beneficiaries in emergency settings by the EMS system as a whole consist of more than simply transporting beneficiaries. Costs may differ for organizations in these situations in important ways; therefore, we agree with the commenters to add one question to the survey that incorporates whether the agency responds to calls with another agency.

After consideration of the comments we added a question in Section 2 of the data collection instrument asking whether the organization responds to calls for service in conjunction with a non-transporting EMS agency, such as a fire department or law enforcement agency. We also added a follow-up question for respondents answering ''yes'' to collection information on (a) the share of ground ambulance responses during which a non-transporting EMS agency provides staff contributing to the response, and (b) the broad roles of these staff (including EMT-Paramedic, other EMT, and other.

(2) Collecting Data on Ground Ambulance Utilization

CMS is required to collect information on the utilization of ground ambulance services. In the proposed rule we stated that while we could collect information on the volume of ground ambulance services that can be billed to Medicare, this approach would not provide information needed to determine total utilization of ground ambulance organizations. We stated another option would be to utilize Medicare claims data for estimates of ground ambulance transport volume and separately collect information on services not payable by Medicare (such as responses that did not result in a transport), but that this approach would also not provide complete information on total transport volume, since other services, such as responses that do not result in a transport, would not be included.

Based on information provided during interviews with ground ambulance organizations, we identified several distinct utilization categories, such as total responses and ground ambulance responses. In the proposed rule, we stated that this is particularly important for fire-based and police-based organizations that may have a significant volume of fire and police responses that do not involve a ground ambulance. We stated that the number of responses that did not result in a transport can be separately tallied. We also stated that other important utilization categories are ground ambulance transports (that is, responses during which a patient is loaded in a ground ambulance), which can be measured in terms of total transports (that is, all ground ambulance transports regardless of payor) or paid transports (that is, transports for which the ambulance provider or supplier was paid in part or in full). Additionally, we stated that another utilization category would include information on ambulance providers and suppliers that furnish paramedic intercept services or

provide paramedic-level staff in the course of a BLS response where another organization provides the ground ambulance transport.

In the proposed rule, we stated we believed it is important to collect utilization data related to all services, not just transports, because other services that contribute to the total volume of responses have direct implications for costs and that collecting utilization information related to transports without collecting information on other services would omit important cost information. We stated that some utilization measures, such as the ratio of ground ambulance to total responses, may be one basis for allocating certain costs reported elsewhere in the data collection instrument. We stated that another example would be the difference between total and paid transport, as this would provide information on services that were provided to patients but for which no payment is received.

To best capture the full range of utilization data, we proposed a two-pronged approach to collect data on the volume and the mix of services. First, we proposed to collect total volume of services for each of the categories listed below in Section 5 of the data collection instrument:

- Total responses, including those where a ground ambulance was not deployed (question 1).
- Ground ambulance responses, that is, responses where a ground ambulance was deployed (question 2).
- Ground ambulance responses that did not result in a transport (question 4).
- Ground ambulance transports (question 5).
- Paid ground ambulance transports, that is, ground ambulance transports where the ambulance provider or supplier was paid for a billed amount in part or in full (question 6).
- Standby events (question 7).
- Paramedic intercept services as defined by Medicare (question 8).
- Other situations where paramedic staff contributes to a response where another organization provides the ground ambulance transport (question 9).

The CAMH report describes several cases where an ambulance provider or suppliers' mix of services within one of the utilization categories described above could affect costs or revenue. Most importantly, within billed transports, variation in the mix of specific ground ambulance services (for example, ALS versus BLS services) will affect both costs (because ALS transports require more and more costly inputs) and revenue (because ALS services are generally paid at a higher rate). We stated that ground ambulance organizations with a higher share of responses that are emergency responses may also face higher fixed costs, and that the costs for organizations furnishing larger shares of water ambulance transports are likely different than costs from organizations that do not furnish water ambulance transports. We stated that there is a subset of ground ambulance organizations that specialize in non-emergency transports or inter-facility transports, which suggests that this business model may result in different per-transport costs compared to EMS-focused ambulance providers and suppliers.

Second, to account for this significant variation, we proposed to collect the following information related to service mix:

- The share of responses that were emergency versus non-emergency (Section 6, question 1).
- The share of transports that were land versus water (asked only of organizations reporting that they operate water ambulances; Section 6 question 2).
- The share of transports by service level (Section 6 question 3).
- The share of transports that were inter-facility transports (Section 6 question 4).

We did not propose that respondents report on their mix of services in primary and secondary service areas (as defined above) separately because this would double the length of this section of the data collection instrument and require complex calculations or use of assumptions by respondents that do not separately track services by area. Instead, we proposed that respondents report the share of total ground ambulance responses that were in a secondary rather than primary service area in a single item (Section 5 question 3). We also did not propose to collect detailed information regarding the mix of services for total transports (versus paid transports) and paid transports (versus total transports) because collecting information on the mix of services for total and paid transports separately would double the reporting burden in this section and because we believed, based on discussions with stakeholders, that it is reasonable to assume that the distribution of transports across categories would be the same.

We received comments on collecting data on ground ambulance utilization and service mix. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that they were pleased that CMS proposed to collect utilization data on all services, not just transports, in Section 3 of the data collection instrument. These commenters stated that they agree with CMS that these data are important because other services that contribute to the total volume of responses have direct implications for costs. They also stated that given the importance of this information to determining and evaluating the costs of providing ground ambulance services, they asked that CMS add ''low,'' ''medium,'' and ''high'' response options to allow the data to be separated by the volume of services provided by each respondent. They stated that while that information might be obtained by adding the various questions in Section 5 of the data collection instrument, adding such a question would allow for evaluators to have a more straightforward and consistent method of taking this critical factor into account. They stated that by setting the definition of low, medium, and high volume, CMS would be standardizing the way in which these terms are used by anyone seeking to use the data to develop policy and that standardization is critically important when policies such as low-volume adjusters are being considered.

Several commenters requested clarifications on the definitions of ''ground ambulance,'' ''response,'' and ''transport, including removing the Medicare definition of 'medically necessary' from the definition of transports because it is not uniform across payers. For items related to service mix, one commenter suggested using the Medicare manual definitions of specific ground ambulance services to avoid confusion. Commenters also suggested clarifications to the definition of ''interfacility transport.''

Another commenter suggested several points of clarification on responses and transports. The commenter stated that it was not clear how to count responses for situations when multiple ambulances may be dispatched to the scene, but not all of them transport beneficiaries. They suggested that responses should actually be the number of ambulances sent to the scene. This same commenter also requested clarification on whether responses where a police car is first on the scene and then cancels the ambulance should be counted in responses, and whether community paramedicine visits should be counted.

One commenter requested clarification about how to treat transfers that are 'emergency.' The commenter noted that in rural areas, transfers can

be considered emergency calls when a patient needs to be transported to a higher level of care. They requested clarification on how an emergency transfer should be counted in the responses and transports. This commenter also requested clarification on how ground ambulance organizations who receive some local tax funding to offset the patients who do not pay should report unpaid transports since in this scenario all patients' transports are partially paid.

Many commenters noted that, while they believe it is important to collect information on responses that do not result in transports, they believed some ground ambulance organizations do not currently track this information. These commenters suggested that CMS add new response options to allow respondents to either estimate the share of responses where the patient is not transported or to report that this information is not available.

Several commenters noted that they incur significant costs for ground ambulance where the patient is pronounced dead at the scene. These commenters asked that CMS add several items to the data collection instrument to collect information on the share of responses that involve a patient pronounced dead on-scene and the time and costs involved in these responses.

Response: We appreciate the detailed comments to our proposals, but do not agree that respondents should be presented with an option to report service volume in terms of categorical ''low,'' ''medium,'' and ''high'' response options. Data collected using this categorical approach would considerably decrease the precision of estimated per-transport costs. We also believe that it would be challenging to combine data from ground ambulance organizations reporting specific counts of services with those opting to use the categorical response options. Reported counts of services can easily be described in terms of categories when the data is analyzed.

We agree that it is appropriate to use Medicare manual definitions for ground ambulance services, although some of the verbatim descriptions may need to be abridged due to their length. We appreciate commenters' concerns that the specific Medicare definition of ground ambulance transport may not apply to transports paid by certain other payers. While we would generally prefer to use the Medicare definition of ground ambulance transports, we believe that the burden of asking respondents to distinguish between transports paid by other payers that would or would not have met Medicare requirements would be unreasonable compared to incremental benefit of using this narrower definition. We agree that the definition of interfacility transport in the data collection instrument needs to be clarified and revised. We agree that the commenters' specific clarifications to the definitions of several service categories will be helpful to respondents.

In the data collection instrument, the term 'ground ambulance response' is defined as ''a response by a fully equipped and staffed ground ambulance, scheduled or unscheduled, with or without a transport, and with or without payment. If more than one vehicle is sent to the scene, the instructions are to count this as one response.'' For example, if three ambulances are sent to one incident, and only one ambulance transports a patient, then this example is counted as one response and one transport. Similarly, responses where another EMS vehicle arrives and cancels the ambulance would not be counted in the responses. While there may be some discrepancy between the number of responses, paid transports and responses that do not result in a transport, we do not agree with the suggestion to allow for multiple ambulances sent to one scene to be counted as multiple responses since we do not encourage ground ambulance organizations to send more than one ambulance on every call.

Emergency transfers would be counted in the number of emergency responses in Section 6, Question 1, and under their corresponding level of service in Question 3. Paid transports should only include those where a health insurer or patient paid for some or all of the billed charge. Any payments that are offset by tax revenue should not be counted in this section since tax revenue is reported separately in the revenue section.

We agree with commenters that it is important to collect information on the number of responses that do not result in a transport, and understand that some ground ambulance organizations many not currently track this information. Due to the importance of this information for determining cost, we do not believe that adding the response options to report that the information is not available or to allow respondents to estimate the share of responses where the patient is not transported is appropriate.

The proposed data collection instrument asks respondents to report the share of responses that do not result in a transport for any reason, including that the death of the patient. We are collecting information on all ground ambulance costs, regardless of whether the patient was transported. Given our overarching goal of minimizing burden while collecting the data necessary, we believe that existing items collecting information on the number of responses that did not result in a transport are sufficient.

After consideration of the comments, we used the Medicare manual definitions of Medicare ground ambulance services, clarified the definitions of other response and transport categories, and removed the Medicare medical necessity requirement from the definition of ''ground ambulance transport.'' We also refined the definition of ''interfacility transport'' in the data collection instrument to include transports where ''the origin and destination are one of the following: A hospital or skilled nursing facility that participates in the Medicare program or a hospital-based facility that meets Medicare's requirements for provider-based status. We also added an additional question to the data collection instrument that specifically asks for interfacility transports that are covered under Medicare Part A where the ambulance provider or supplier would seek payment from SNF, hospital, or hospice.

Finally, we clarified the instructions for the definitions of response and transports, incorporating the example of an emergency transfer.

(3) Collecting Data on Costs

Section 1834(l)(17)(A) of the Act requires CMS to collect cost information from ground ambulance organizations. This section describes the data in each cost category that we proposed to collect, as well as alternatives that we considered.

In the proposed rule we stated that the costs reported separately in the categories of costs we proposed to collect would sum to an organization's total ground ambulance costs. In addition to ground ambulance costs, we proposed to ask all respondents in the data collection instrument to report their total annual costs (that is, operating and capital expenses), inclusive of costs unrelated to ground ambulance services, in a single survey item (Section 12, question 1). For ground ambulance organizations that do not have costs from other activities (such as from operating a fire or police department), the reported total costs are a way to cross-check costs reported in individual cost categories throughout the data collection instrument, and we can compare the reported total to the sum of costs across categories. In the proposed rule, we stated that such a

cross-check may also be appropriate for ground ambulance organizations with costs from other activities, as the sum of costs across ground ambulance cost categories should always be less than the ground ambulance organization's reported total costs. We stated that we believed that this cross-check will improve data quality and is consistent with existing survey-based data collection tools and that this approach would provide a better understanding of the overall size and scope of ground ambulance organizations, including activities other than providing ground ambulance services and that relatively larger organizations may have lower ground ambulance costs due to due to economies of scale and scope.

To avoid reporting the same costs multiple times, we included instructions and reminders throughout the data collection instrument to avoid double-counting of costs. We stated that from a design perspective, we believe it is less important where a particular cost is reported on the data collection instrument and more important that the cost is reported only once.

We made two proposals that have important implications for reporting in all cost sections in the data collection instrument. First, in the case where a sampled organization is part of a broader organization (such as when a single parent company operates different ground ambulance suppliers), we proposed to ask the respondents to report an allocated portion of the relevant ground ambulance labor, facilities, vehicle, supply/equipment, and other costs from the broader parent organization level in separate questions in several places in the cost sections of the data collection instrument (Section 7.2 question 3, Section 8.2 question 2, Section 8.3 question 2, Section 9.2 question 5, Section 9.3 question 6, Section 10.2 question 4, and Section 11 questions 2 and 5). This scenario is discussed in more detail in the sampling section below. In exploratory analyses, we found that a small share of NPIs were part of broader parent organizations. Due to the rarity of this scenario and the complexity of calculations required, we proposed to allow the respondent to report an allocated amount directly for these questions using an allocation approach they regularly use for this purpose. We stated that while a specific allocation approach would yield more uniform and transparent data, we believed that these benefits were not worth the additional respondent burden.

Second, we proposed to include a general instruction stating that in cases where costs are paid by another entity with which the respondent has an ongoing business relationship, the respondent must collect and report these costs to ensure that the data reported reflects all costs relevant to ground ambulance services. We provided examples including when a municipality pays rent, utilities, or benefits directly for a government or non-profit ambulance organization, or when hospitals provide supplies and/or medications to ground ambulance operations at no cost. During interviews with ground ambulance organizations, we were told that there are many nuanced arrangements that fit this broad scenario. In the proposed rule, we stated that although we recognized this would be an additional step for some ground ambulance organizations, we are concerned that the lack of reported cost data in one of these major categories could significantly affect calculated total cost.

Because some ambulances, other vehicles, and buildings are donated to ground ambulance organizations, we stated that we considered asking respondents to report fair market values for these vehicles and buildings. We stated our concern that the lack of reported cost data in one of these major categories could affect calculated total cost, as well as our understanding that it is not always clear what cost is appropriate to report. To avoid the subjectivity and burden involved in asking respondents to report fair market value, we proposed that respondents report which ambulances, other vehicles, and buildings have been donated, but not an estimate of the fair market value of those donations. We stated we believe fair market values could be imputed using publicly available sources of data to facilitate comparison of data between organizations that have donations and those that do not. For the same reasons, we also proposed not to collect an estimate of fair market value for donated equipment, supplies, and costs collected in the ''other costs'' section of the data collection instrument. We stated that for those ground ambulance organizations with costs that were paid by another entity with which the respondent has an ongoing business relationship, such as a ground ambulance organization that is part of or owned by a government entity, respondents would obtain the cost information directly from that entity since we would not consider these to be donated items.

We received general comments on collecting data on ground ambulance costs. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of the categories of costs that we proposed for the data collection system. Commenters stated that they support collecting total ground ambulance costs across all cost data elements, without limiting the costs to those associated with transports and as a result, the cost of readiness will be embedded in the response for each cost category and then be automatically allocated across the services provided. However, one commenter suggested including an explicit question to measure readiness costs: Total trip time multiplied by total responses divided by total scheduled ambulance unit hours (total ambulance labor hours reported for a week divided by 2 as typically there are 2 personnel on an ambulance).

Commenters were also supportive of the proposal to have respondents report total annual costs that include the operating and capital expenses inclusive of costs unrelated to ground ambulance services in a single survey question, as well as CMS' efforts to eliminate double-counting of costs. Several commenters requested clarification that the total cost and total revenues section include non-ground ambulance related costs/revenues.

Commenters stated that they in general support the allocation rules as proposed. Several commenters recommended collecting costs paid by another entity in the data collection instrument and for inclusion in any analysis of Medicare margins so that the costs will not be artificially low and provided the example of including the labor provided by non-transporting organizations at the scene. Another commenter was concerned it may be difficult to obtain costs paid for by other entities for which they have an ongoing business relationship such as a municipality paying for dispatch services.

Commenters supported CMS' proposal to ask reporting ground ambulance organizations that are part of broader parent organizations (for example a broader for-profit corporation billing Medicare for ground ambulance services under multiple NPIs) to submit information related to an allocated share of their parent organization's costs. One commenter specifically recommended that CMS use the term ''central office'' rather than ''parent organization'' in the data collection instrument and suggested that CMS specify a specific allocation methodology that respondents must follow in this scenario to avoid concerns of differences in how these costs are reported across organizations. Another commenter asked that CMS take the

reported estimates of allocated parent organization costs in good faith, without the threat of audits as the data may be difficult for organizations to report, particularly in the initial years of data collection.

One commenter requested that respondents be asked to estimate the fair market value of any ambulances, other vehicles, and buildings that have been donated, rather than relying on CMS or MedPAC to impute these values. The commenter stated they believe respondents could be given the option of identifying the estimated value as of the year the item was donated (and the year it was donated), if that is less burdensome than estimating the current value. They thought that respondents would be in a much better position to accurately estimate these values than CMS or MedPAC.

One commenter stated that many small ground ambulance organizations do not keep track of data on depreciation and was concerned that any of the sections asking for depreciation would be difficult to fill out for some ground ambulance organizations.

Response: The survey is designed to collect information on total costs, which implicitly captures all costs related to readiness, and therefore, we do not believe it necessary to include a separate question that requires ground ambulance organizations to calculate a readiness cost.

We believe that while some commenters noted the lack of a standard approach to the allocation of costs between ambulance organizations and their parent organization or central office could potentially lead to differences in how these costs are reported, we do not believe that developing a specific, standardized allocation method for these costs is necessary, as we expect only a small share of reporting ground ambulance organizations to allocate parent organization costs in this way.

The questions for total costs and total revenue currently specify that services not related to ground ambulance services should be included, but we agree with the commenter suggesting the addition of a question on fees paid to other non-transporting organizations for their services, when there is an agreement in place to pay for these services. However, as we discuss elsewhere in these comments, we continue to believe that requiring ground ambulance organizations to report on the estimated costs of labor, supplies, vehicles, etc. for non-transport vehicles that are 'in-kind' donations would be extremely burdensome for ground ambulance organizations that do not currently pay for these services. However, if a cost that is borne directly by the ground ambulance organization or another entity that owns, operates, or manages the ground ambulance organization, then that cost is required to be reported.

We acknowledge that certain items such as depreciation will be difficult for some agencies to estimate and we will provide additional instructions on how to estimate depreciation in the survey instructions. However, we disagree with the commenter regarding collecting fair market value from respondents because we want to reduce any subjectivity and burden involved in asking respondents to report fair market value. We continue to believe fair market values could be imputed using publicly available sources of data to facilitate comparison of data between organizations that have donations and those that do not. We believe the data collected on the survey will allow end users to infer approximate costs for donated items.

After consideration of the comments, we added a question to the 'other costs' section for funds paid to other organizations for services (such as non-transporting organizations providing medical personnel).

(i.) Collecting Data on Staffing and Labor Costs

As we discussed in the proposed rule, ambulance organizations told us in interviews that labor is one the largest contributors to total ground ambulance costs (especially medical staff such as EMTs, paramedics, and medical directors). They told us that they use a broad mix of labor types and hiring arrangements, and that there is significant variation in tracking staffing and labor cost inputs that are needed to calculate costs. We were also informed by ambulance organizations that data on the number of ground ambulance staff and associated labor costs were often available at one of three levels: The individual employee level; aggregated by category such as EMT-Basic or Medical Director; or aggregated across all staff. Additionally, we were told by ambulance providers and suppliers that ground ambulance organizations typically face challenges in tracking ground ambulance staff and costs by category when staff had multiple ground ambulance responsibilities (for example, EMTs with supervisory responsibilities, EMTs who are also firefighters, etc.).

In the proposed rule we stated that we agree that labor costs are an important component of total costs and believed that it is necessary to collect information on both staffing levels, that is, the quantity of labor used, and the labor costs resulting from these labor inputs. Without information on staffing levels, we stated we would not be able to gauge whether differences in labor costs are due to compensation or different levels of staffing. We further stated that collecting information on staffing levels allows the use of imputed labor rates from other sources (such as the Bureau of Labor Statistics). We also acknowledged the practical need to balance the burden involved in reporting extremely detailed staffing and labor costs information against the usefulness of detailed data for explaining variation in ground ambulance costs. Therefore, we proposed to collect information in the data collection instrument on the number of staff and labor costs for several detailed categories of response staff in Section 7 of the data collection instrument. This includes medical staff such as EMT-basic, EMT-intermediate, and EMT-paramedic, a single category for paid administrative and facilities staff (for example, executives, billing staff, and maintenance staff), and a single category for medical directors. We stated we believed this approach involves less respondent burden compared to reporting on each individual staff member. If more detailed categories were used for reporting staffing levels and costs, we stated we believed the burden involved in assigning paid administrative and facilities staff with multiple roles to individual categories or apportioning their labor and costs to separate categories would increase.

We stated that the main limitation of our approach is that we would not collect detailed information on specific paid administration and facilities labor categories. Therefore, we also proposed to collect some information that would help explain variation in labor costs by asking whether the ground ambulance organization has some staff in more specific paid administration and facilities categories such as billing, dispatch, and maintenance staff (Section 7, question 1). We stated this question serves as a screening question to determine which response options appear to the respondent in several other questions in this section of the data collection instrument. We also proposed to ask for information on why individual labor categories are not used (Section 7, question 1) and if there is at least one individual with 20 hours a week or more of effort devoted to specific activities such as training and quality assurance (Section 7.2, question 2).

Reporting Staffing Levels

In reporting staffing levels in the data collection instrument, we stated that we considered several approaches. One approach we considered was asking the respondent to report only the number of staff (that is, counts of people). Under this approach, a part-time employee would count as ''1'' to the number of staff even if they worked a small number of hours per week. We stated we believed this approach would result in less accurate reporting of labor inputs, especially from organizations relying heavily on part-time staff or staff with responsibilities unrelated to ground ambulance services. We also considered allowing respondents to report full-time-equivalent (FTE) staff on a 40-hour per week basis, but ground ambulance organizations informed us that reporting FTEs would be burdensome. As a third approach, we considered asking respondents to report ground ambulance staffing levels in terms of hours over a reporting year. We stated that reporting labor hours over the entire reporting year allows for more accurate reporting of staff working part-time and may involve less burden for respondents that already tally annual labor hours (for example, via payroll records), but would likely be difficult for those who do not already track labor hours in this manner. As a fourth approach, we considered asking respondents to report ground ambulance staffing levels in terms of hours worked during a typical week. We stated that reporting staffing levels in terms of hours worked either over a reporting year or during a typical week allows detailed accounting of part-time staff and staff with ground ambulance and other responsibilities and involves fewer calculations and adjustments than reporting FTEs. We also stated that reporting in terms of hours over a typical week has the additional advantage of simplifying reporting for staff that start or stop work during the 12-month reporting period. We further stated that the main limitation of reporting staffing levels in terms of hours over a typical week is that the week that the respondent selects for reporting may not be generalizable to other weeks in the reporting period.

In the interest of minimizing reporting burden, we proposed to collect information on the number of staff in terms of hours worked over a typical week (Sections 7.1 and 7.2). The instructions in the data collection instrument asked respondents to ''select a week for reporting that is typical, in terms of seasonality, in the volume of services that you offer (if any) and staffing levels during the reporting year.''

Scope of Reported Labor Costs

For the purposes of collecting information on labor costs, we proposed to define labor costs to include compensation, benefits (for example, healthcare, paid time off, retirement contributions, etc.), stipends, overtime pay, and all other compensation to staff. We referred to these costs as fully-burdened costs. We stated that some ambulance providers and suppliers track compensation but not benefits because another entity, such as a municipality, pays for benefits, and that the ability of these ambulance organizations to report fully burdened costs may be limited. We stated that despite this limitation and due to the importance of labor costs as a component of total ground ambulance costs that we believed information on fully burdened costs (Sections 7.1 and 7.2) must be reported so that all relevant ground ambulance transport costs are collected. We stated that ground ambulance organizations selected to report data may need to implement new tracking systems or request information from other entities (such as municipalities) to be able to report fully-burdened labor costs.

Volunteer Labor

In the proposed rule, we stated that ground ambulance organizations have also informed us that a significant share of ambulance organizations rely in part or entirely on volunteer labor and that the systems and data available to track the number of volunteers and the time that they devote to ground ambulance services varies. We proposed to collect information on the total number of volunteers and the total volunteer hours in a typical week using the same EMT/response staff and administrative and facilities staff categories used elsewhere in the data collection instrument (Section 7.3, questions 1–5). We stated the although some suggested that assigning a value to volunteer labor hours may be important, the data collection instrument collects information only on the amount of volunteer labor (measured in hours in a typical week) and not a market value for that labor. We also stated that we believed reported hours can be converted, if necessary, to market rates using data from other sources. We proposed to collect the total realized costs associated with volunteer labor such as stipends, honorariums, and other benefits to ensure all costs associated with ground ambulance transport are collected (Section 7.3, question 6).

Allocation and Reporting Staff With Other Non-Ground Ambulance Responsibilities

Since firefighter/EMTs are common in many ambulance suppliers, we proposed to ask respondents that share costs with a fire or police department to report total hours in a typical week for paid EMT/response staff with fire/police duties only (Section 7.1). In the proposed rule, we stated we believed this information could be used to subtract a portion of associated labor costs when calculating ground ambulance labor costs. We stated we believed our approach is more consistent and involves less burden than asking respondents to perform their own allocation calculations necessary to report only the hours or full-time equivalents related to ground ambulance services.

As already noted, many ground ambulance organizations have staff with responsibilities beyond ground ambulance and fire/police response. To account for these scenarios, we proposed to ask respondents to report the total hours in a typical week unrelated to ground ambulance or fire/police response duties (which are addressed separately as described in Section 7.1), as the costs associated with this labor can be subtracted by those analyzing the data when calculating ground ambulance labor costs. We stated we believed this approach provides both transparency and consistency in the data with minimal burden, and may avoid scenarios where all of the costs associated with staff with limited ground ambulance responsibilities contribute to total ground ambulance costs.

We received comments on collecting data on collecting labor costs. The following is a summary of the comments we received and our responses.

Comment: All commenters supported the collecting of information on staffing and labor costs. They stated that they agree that labor is a major driver of the cost of ground ambulance services; thus, despite the fact that it may be difficult for some organizations to report full labor-related costs, they should be encouraged to do so to allow CMS and others to understand the full cost of labor, including compensation, benefits (for example, healthcare, paid time off, retirement contributions, etc.), stipends, overtime pay, and all other compensation to staff.

Commenters also stated that understanding and accounting for volunteer hours is an important

component of ground ambulance costs and that they agree with our proposals to collect information on the total number of volunteers and the total volunteer hours in a typical week using the same EMT/response staff and administrative and facilities staff categories used elsewhere in the proposed data collection instrument, as well as the decision to collect only hours and allow those analyzing the information from the data collection instrument to use appropriate proxies for placing a value on the cost of volunteer labor. Additionally, they stated that they support the CMS proposal to have respondents who also provide fire or public safety services to report the hours of their EMTs in a manner that will allow those using the data to subtract the portion of the associated labor costs that is not attributable to ground ambulance labor costs. They stated that the data collection system must ensure that the costs used to assess Medicare payment rates are specific to the provision of ground ambulance services and not mixed with the costs associated with other services that an organization might provide.

Several commenters made specific recommendations related to the definitions used in this section of the data collection instrument. Some commenters were concerned that the instruction to exclude staff and labor costs related to staff with responsibilities in ''healthcare delivery unrelated to ground ambulance'' could be interpreted to include EMT and other response staff arriving on the scene via a vehicle other than a ground ambulance. Another commenter asked that CMS clarify the scope for costs related to volunteer labor ''stipends and/or benefits''.

Several commenters made specific recommendations related to improving the instructions for this section of the survey. One commenter expressed concern that CMS may be biasing certain reported staffing and cost information by asking respondents to categorize staff based on their roles or certification at the start of the reporting period. Other commenters requested clarification on how to report information for staff who work in both response and administrative roles. One commenter requested clarification on how respondents should select a ''typical week'' over which staffing levels should be reported and recommended replacing the typical week approach with an approach based on dividing hours worked annually by 52. The same commenter also requested clarification on how the labor costs associated with medical directors should be reported and recommended separate reporting on staffing and costs for medical directors who are employees and those who are contractors. Another commenter requested clarification about the reporting of hours for volunteers who might be on call with pagers.

Some commenters suggested adding additional items to capture more information on how labor from partner organizations (that is, other entities sending response and other staff to respond to calls for service) contribute to overall responses. One commenter specifically suggested that CMS ask for counts of total staff for different types of responses so that CMS can better understand different staffing and deployment models.

Several commenters stated that throughout the proposed rule, CMS mentioned their intention to calculate the value of services performed by volunteer personnel by benchmarking their number of hours served against the average wage data collected by the Bureau of Labor Statistics. They stated that the Bureau of Labor Statistics' current processes for gathering wage information for EMS personnel is inaccurate as it pertains to cross-trained firefighter/EMTs and firefighter/paramedics. Another commenter suggested using another database called Independent Sector to determining the value of volunteer labor.

Response: We thank commenters for their support. We considered several alternatives when developing our proposals for collecting information on staffing and labor costs, including approaches that would have allowed respondents to split reported hours and labor costs across multiple staff categories for individual staff with multiple responsibilities. While these alternatives could collect more detailed information, they would all increase response burden substantially. The proposed instructions ensure that all compensation costs are reported, and no compensation costs are double counted. The instructions accomplish this by aiming to direct respondents to assign each individual staff member to only one labor category. While CMS recognizes the instructions are lengthy, the aim is to minimize necessary calculations and complex data tracking by the respondent.

It appears that several commenters mistakenly assumed that we proposed to collect compensation costs over a typical week rather than over the entire annual reporting period. While we did propose to collect information on staffing levels over a typical week, the data collection instrument collects compensation costs only on an annual basis. Collecting annual compensation minimizes some of the concerns raised by commenters related to under or over-estimating labor costs in a particular category. The distinction between reporting *staffing levels* during a typical week and labor costs over the entire year may have introduced unnecessary complication, and therefore, we are removing the instruction to report staffing levels during a typical week and instead will ask respondents to report staffing levels in terms of hours over the entire annual reporting period.

The proposed data collection instrument instructions ask respondents to report costs associated with contracted medical director services in Section 11 of the data collection instrument as an ''other cost.'' We agree with commenters that separating questions related to medical directors is confusing particularly given the fact that contracted medical directors are so common.

In reporting the hours associated with volunteer labor, it was not our intention to capture hours on-call while volunteers are at other locations or jobs. We intended to capture the hours in service, which includes the time from which they receive a call or a page to the time they are finished with their call, as well as time spent in the station house performing duties as if they were being paid.

We agree that it would be possible to collect information that would help explain differences in staffing and deployment models, although collecting this information would add additional burden on respondents. The current labor questions collect what we believe is the most relevant information to assess how differences in labor inputs drive total costs—more specifically, the data collection instrument collects information on the total staff and total compensation. We agree that it is important to understand the extent to which other organizations contribute to responses, for example by providing paramedic or other staff to responses that are not paid by the organization submitting data. While the proposed data collection instrument collects costs related to these arrangements when a payment is made, the proposed data collection instrument does not otherwise collect information on when such arrangements exist, which we agree would be helpful information to include in the data collection instrument.

Comment: One commenter stated that using the Bureau of Labor Statistics is one method of valuing volunteer labor but provided an alternative method for

valuing volunteer labor using Independent Sector data. Another commenter stated that the BLS' current processes for gathering wage information for EMS personnel is inaccurate as it pertains to cross-trained firefighter/EMTs and firefighter/paramedics. Commenters also stated that the definition of stipends and benefits for volunteer labor should be broadened to include all forms of compensation from the ground ambulance organization such as insurance, stipends, or other forms of compensation.

Response: We did not specify the use BLS or any other source of wage data to determine the valuation of volunteer labor in the proposed rule in order to provide flexibility in valuing volunteer labor when analyzing the data. The data collection instrument collects information on volunteer hours and total compensation of any type from the ground ambulance organization so we agree that the definition of ''stipends and/or benefits'' should be broadened to include all forms of compensation from the ground ambulance organization such as insurance, stipends, or other forms of compensation.

After consideration of the comments, we are removing the instruction to report staffing levels during a typical week and instead will ask respondents to report staffing levels in terms of hours over the entire annual reporting period. This will result in reporting instructions that are more similar for staffing levels and labor costs. We are not changing the instructions that ask respondents to categorize each staff member in only one category. While alternative approaches could collect more accurate and detailed information, we believe these alternatives would involve significant additional burden. We are adding new items to the labor section asking (1) whether another organization provides staff in certain labor categories (including paramedic, other EMT, and other) to responses where the sampled ground ambulance organization would transport the patient, and (2) what share of responses involve labor from other organizations in these categories. We believe these additions will help CMS understand when reported labor costs may be lower due to contributions to responses from other organizations.

To minimize confusion and potential double-counting of costs associated with medical directors, we are moving the specific question related to contracted medical director service costs from the other costs section, Section 11, to the labor section, Section 7, in the data collection instrument. We are editing the definition of ''stipends and/or benefits'' in relation to volunteer compensation to include all compensation provided by the ground ambulance organization. Organizations should only report the costs they pay for a medical director, not an estimated true cost for the value of that medical director's labor. We will also clarify the instructions surrounding the calculation of volunteer hours to include time spent in service for all volunteers. We are also editing the instructions in this section to clarify that staff participating in ground ambulance responses should be included regardless of how they arrive on the scene.

(ii.) Collecting Data on Facility Costs

Facility costs may include rent, mortgage payments, depreciation, property taxes, utilities, insurance, and maintenance, and the associated costs vary widely across ambulance providers and suppliers. Some ground ambulance organizations own facilities while for others, rent, mortgage, or leasing is an important component of total operational costs. Some ground ambulance organizations share facilities with other operations (such as fire and rescue services), and individual ground ambulance organizations often operate out of several facilities of different types, sizes, and share of space related to ground ambulance operations.

In the proposed rule, we considered requiring respondents to report facility costs aggregated across all facilities. We stated we believed this approach would minimize burden on the respondent by eliminating the need to break costs down by facility but that it may also increase the risk for inconsistencies in how respondents report total facilities costs. We stated that under this approach, respondents whose ground ambulance organizations share operational costs with a fire department or other entity would need to calculate and report an estimate of facilities costs that was relevant only to ground ambulance services.

We also considered requiring respondents to report all costs on a per-facility basis. We stated we believed this approach would allow the most flexibility in reporting complex facility arrangements from ground ambulance organizations operating out of multiple facilities. We further stated that this approach may also involve more burden, particularly for larger organizations, to report costs on a facility-by-facility basis, and many organizations do not track costs such as maintenance or utilities on a per-facility basis.

We proposed a hybrid approach involving both per-facility and aggregate reporting of different information. We stated that first respondents report the total number of facilities (Section 8., questions 1–2) and then indicate for each facility whether they paid rent, mortgage, or neither during the reporting period, total square footage, and share of square footage related to ground ambulance services (Section 8.1, question 3); second, respondents report their per-facility rent, mortgage, or annual depreciation (Section 8.2); and third, respondents report facilities-related insurance, maintenance, utilities, and property taxes aggregated across all facilities (Section 8.3).

We stated that we believe this approach allows for the collection of the information needed to calculate a total facilities cost related to ground ambulance services while avoiding a burden on respondents to calculate allocated facility costs. We stated that total insurance, maintenance, utility, and property tax costs can be allocated using reported square footage and shares of square footage related to ground ambulance services. We further stated that the approach requires respondents to provide both the square footage of each facility, and the share of square footage for the facility that is related to ground ambulance operations. We stated that we expect some ground ambulance organizations would have this information available and others would need to collect this square footage information to report along with facilities costs, but did not believe this information would will be difficult to collect.

We received comments on collecting data on facility costs. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that they support the proposals related to facility costs and had no additional suggestions. One commenter requested further guidance on how ground ambulance organizations should interpret the percentage of their facility square footage directly attributable to ground ambulance services. They asked if CMS is just looking for the space used to park the ambulance and store EMS supplies, how ground ambulance organizations should categorize common spaces, and what portion of the chief's office should be designated as being attributable to ground ambulance services.

Response: We are not specifying a particular methodology for calculating the percent of square footage attributable to ground ambulance services, in order to reduce the burden on organizations who might have a particular method in place already. The

instructions in Section 8 of the data collection instrument ask for the total square footage of the facility and the percentage of the facility related to ground ambulance services. The entire square footage of the facility should be reported in the first case.

After consideration of the comments, we provided additional examples for clarification on how a ground ambulance organization should report the percentage of the facility attributed to ground ambulance services in the data collection instrument.

(iii.) Collecting Data on Vehicle Costs

Section 1834(l)(17)(A)(ii) of the Act requires CMS to collect information on ''the utilization of capital equipment and ambulance capacity.'' We proposed to collect information on the number of ground ambulances and other vehicles related to providing ground ambulance services, as well as the costs associated with these vehicles to meet these requirements.

In the proposed rule, we stated that ambulance organizations operate ground ambulances, as well as other vehicles to support their ground ambulance operation, and some may have a variety of other vehicles that are associated with ground ambulance responses. We provided the example of a fire truck staffed with fire personnel cross-trained as EMTs that may respond with a ground ambulance to an emergency call. We stated that other vehicles might be used in responses and may be referred to as a non-transporting EMS vehicle, a quick response vehicle, a fly-car, or an SUV that carries a paramedic to meet a BLS ambulance from another organization during the course of a response.

We considered two alternatives for collecting vehicle costs in the proposed rule. One alternative was to only include the costs for ambulances and exclude other certain non-ambulance response vehicles from reported costs. We stated that we believe that excluding other certain non-ambulance response vehicles from reported costs could potentially result in underreporting of total ground ambulance costs, particularly among those providers or suppliers that rely heavily on these vehicles to support their ground ambulance services. Another alternative we considered was to include the costs of all vehicles that are used as part of ambulance services, such as quick response vehicles that are used to supplement ambulances.

For all vehicles, vehicle costs can be reported either in aggregate or on a per-vehicle basis. We stated that we believe that while reporting vehicle costs in aggregate may involve less burden for some respondents, those respondents that do not track aggregated costs would still require a tool to enter information on per-vehicle basis. Furthermore, we stated we believed that aggregated costs for vehicles other than ground ambulances offer analysts with fewer alternatives to allocate a share of vehicle costs to ground ambulance services.

We proposed to collect data on vehicle costs in the data collection instrument in two parts: Ground ambulance vehicles (Section 9.1); and all other vehicles related to ground ambulance operations (Section 9.2). For ground ambulance vehicles, we proposed to collect information on the number of vehicles, total miles traveled, and per-vehicle information on annual depreciated value (and remounting costs if applicable) for owned vehicles, and annual lease payments for rented vehicles (Section 9.1, questions 1–4). We considered proposing to collect the necessary information to calculate annual depreciated value using a standardized approach. However, we proposed to allow respondents with owned vehicles to use their own accounting approach to calculate annual depreciated value per vehicle. We stated we believed that allowing flexibility for respondents to use their standard approach for this calculation would result in more accurate data and less reporting burden.

We also proposed to use a similar approach to collect per-vehicle information for owned and leased vehicles of any other type that contribute to ground ambulance operations, including fire trucks, quick response vehicles, all-terrain vehicles, etc. (Section 9.2, questions 1–5). We stated that the proposed instructions in Section 9.2 of the data collection instrument specified that reported vehicles must support ground ambulance services. We proposed to collect the type of each vehicle in broad categories in addition to the annual depreciated value or lease payment amount for each vehicle.

In addition to the above costs, we also proposed to collect aggregate costs associated with licensing, registration, maintenance, fuel, insurance costs for all vehicles combined (ambulance and non-ambulance) (Section 9.3, questions 1–5). We stated we believe that these costs are often aggregated within providers' and suppliers' records and that reporting in aggregate form may reduce respondent burden with minimum risk for reporting error.

When estimating total ground ambulance vehicle costs for ground ambulance organizations that share operational costs with fire and police response or other non-ground ambulance activities, we stated that a share of vehicle costs reported via the data collection instrument will need to be allocated as vehicle costs related to ground ambulance services. One alternative we considered to do this was simply to ask respondents about the share of costs associated with ground ambulance services as we thought this would be the least burdensome approach; however, we stated that we believed data collected in this manner would not allow for estimation of costs associated with non-ground ambulance vehicles that support ambulance services. We considered another alternative where (1) the ratio of ground ambulance to total responses would be used to allocate costs associated with non-ambulance vehicles, (2) the total number of vehicles would be used to allocate aggregate costs associated with licensing, registration, maintenance, and fuel costs, and (3) depreciated annual costs and/or lease payment amounts would be used to allocate insurance costs. We stated that the main limitation of this approach is that maintenance and fuel costs could vary significantly across vehicle categories. We provided the example that maintenance and fuel costs may be significantly different for ground ambulance than for other types of vehicles. As a result, we proposed a modification of this alternative where we also ask respondents to list percent of total maintenance and fuel costs attributable to each type of vehicle (that is, ground ambulances, fire trucks, land rescue vehicles, water rescue vehicle, other vehicles that respond to emergencies such as quick response vehicles, and other vehicles; Section 9.3, questions 4 and 5). We proposed to also ask respondents to report total mileage for ground ambulance (land and water separately) and total mileage for other vehicles related to ground ambulance responses (land and water separately) as a potential alternative means to allocate fuel and maintenance costs.

We received comments on collecting data on vehicle costs. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that they generally support the approach to collect vehicle cost data. Many commenters stated that they agree it will be easier for ground ambulance organizations to track their total vehicle costs and report that information than try to allocate the vehicle costs between ''loaded'' (or response) hours/miles and the costs incurred when the vehicles are not being used to respond directly to a

request for service (for example, a 911 call). They stated that this approach would work across the major cost centers outlined in the proposed rule. They stated that they understand that CMS has sought to strike a balance between asking for detailed information and not imposing an overwhelming burden on ground ambulance organizations. They stated that while they believe it may overstate the costs to aggregate those associated with licensing, registration, maintenance, fuel, insurance costs for all vehicles combined, both ambulance and non-ambulance, they appreciate the interest in reducing the burden on respondents when reporting such information. They stated that they also support differentiating between vehicles that function as ground ambulances and those that do not. They requested clarification on whether the definition of a ground ambulance refers to the CMS definition or to the definitions that apply in the respondent's state or locality. One commenter suggested adding more general examples of non-ambulance vehicles.

One commenter requested clarification about how to handle the reporting of fire trucks specifically, in cases where a fire truck with EMS personnel may be sent to the scene as part of a response. This fire truck could be owned by the organization filling out the survey, or another non-transporting fire truck from a different organization. This same commenter also requested clarification on how to report insurance costs when these may be paid by another agency, such as a state agency that purchases insurance on behalf of all of the vehicles in its fleet.

Response: We agree that it is important to balance burden on respondents with the level of detail of vehicle data reported in this section. While some data, for example licensing, registration, maintenance, fuel, insurance costs, could be collected in more detail in relation to ground ambulance services, we believe that alternatives to collect more detailed data would involve significant additional burden. Our intention is for organizations to report the ambulances that qualify as such in their jurisdiction. We expect that most of these ground ambulances would meet CMS' definition of a ground ambulance.

It is our intention in the vehicles section to collect data on the costs of vehicles associated with the reporting organization only. This may include fire trucks if the fire trucks are sent to the scene with EMS personnel. If there are no firefighters co-trained as EMS personnel, then these fire trucks are not related to ground ambulance service and should not be included. If an organization is assisted by another organization at the scene (such as from a different fire department), the costs associated with these vehicles would not be included. We state elsewhere in these comments that we will add an additional question to the miscellaneous costs that allows organizations to report fees paid to other non-transporting organizations for their services. We believe that it would be too much additional burden to ask organizations to assess the costs of providing services for organizations other than their own.

For insurance, fuel or other vehicle-related costs, we ask that organizations ask the agency providing these items for an estimate of their cost.

After consideration of the comments, we added more general examples of non-ambulance vehicles, such as sport utility vehicles and pickup trucks used to support ground ambulance services, which should be included in reporting in this section. We also clarified in the data collection instrument that respondents should report on all ground ambulance vehicles that meet local and state requirements.

(iv.) Collecting Data on Equipment and Supply Costs

In our interviews with ground ambulance organizations, we were told that not all ground ambulance organizations would be able to report detailed item-by-item equipment and supply information, and that some organizations have far more sophisticated inventory tracking systems than others that would allow them to report detailed information within a category.

In the proposed rule, we stated we considered alternative approaches related to reporting equipment and supply costs that varied primarily on the level of detail for reporting. We considered extremely detailed data reporting as it would be potentially useful to identify variability in costs across organizations. However, as noted above, we stated that many ground ambulance organizations may not keep detailed records of all their individual equipment and supply costs. Taking those factors into account, we proposed to request total costs in a small number of equipment and supply categories rather than itemized information for all equipment and supply categories (Section 10). We stated these would include:

- Capital medical equipment.
- Medications.
- All other medical equipment, supplies, and consumables.
- Capital non-medical equipment.
- Uniforms.
- All other non-medical equipment and supplies.

We also considered whether to have respondents report both medical and non-medical equipment and supplies together. We stated that we believed that the majority of medical supplies are more likely to be related to ground ambulance services than non-medical supplies for organizations with shared services, and therefore, we proposed to collect this information separately.

Reporting of Capital Versus Non-Capital Equipment

To meet the requirement in section 1834(l)(17)(A)(ii) of the Act to collect information to facilitate the analysis of ''the utilization of capital equipment,'' we proposed to separately collect information on capital equipment expenses (rather than equipment-related operating expenses). Capital equipment (both medical and non-medical) yield utility over time, which we stated can vary depending on the expected service life of the specific good. We stated that in addition to the cost of purchasing or leasing durable goods equipment, depreciation and maintenance costs must be considered in the total cost calculations. Since ground ambulance organizations often track capital equipment on an itemized level, separating items of significantly different age and cost is necessary to calculate depreciation. Therefore, to minimize burden by aligning reporting with the accounting approaches used by respondents, we proposed to ask for capital (Section 10.1, question 1; Section 10.2, question 1) and non-capital costs (Section 10.1, questions 2–3; Section 10.2, questions 2–3) separately so that respondents could report annual depreciated costs for capital equipment and total annual costs otherwise. We also proposed to allow respondents to report annual maintenance and service costs for capital equipment because ground ambulance organizations have stated during interviews that these costs can be significant compared to purchase costs or annual depreciated costs. Finally, we proposed to allow respondents to use their own standard accounting practice to categorize equipment as capital or non-capital. We stated that while we believe it would be possible to ask respondents to use a standard approach, we believed this would require respondents with another practice to recalculate annual depreciated cost and potentially increase respondent burden and reporting errors.

Allocation of Shared Costs

During interviews with ground ambulance organizations, it was noted that although the vast majority of equipment and supplies are for ground ambulance services, some costs are shared with hospitals or clinics. We stated that we believed separate reporting on medical and non-medical equipment and supplies would facilitate allocation (Section 10.1, versus Section 10.2). For organizations that indicate the use of shared services, we proposed to ask separately what share of medical and non-medical equipment and supply costs are related to ground ambulance services (Section 10.1, questions 1c, 2a; Section 10.2, questions 1c, 2a, 3a). We stated the share of non-medical equipment and supplies used for ambulance services may vary for respondents with operations beyond ambulance services. While other allocation methods (such as the share of responses that are ground ambulance responses) may be appropriate to allocate equipment and supply costs, asking respondents to provide their estimate of the share of equipment and supply costs related to ambulance services reduces assumptions made about how best to apply allocation across the various equipment and supplies reported.

We received comments on collecting data on equipment and supply costs. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed a desire to work with CMS to develop additional categories for the cost of equipment, consumables, and supplies for future surveys that would allow policy-makers to address high-cost products or patients who require services resulting in higher costs. They stated that they support the differentiation between capital and non-capital equipment, as well as the proposed allocation rules, and questioned whether nebulizers, which are devices for producing a fine spray of liquid for inhaling a drug, should be considered capital equipment. Another commenter stated that some organizations may not separately report medication costs from other supplies and equipment, and questioned why this was important to separate.

Response: While there are many other potential equipment and supply categories that could have been added separately to this section, in the interest of balancing the level of detail collected in the data collection instrument with burden, we decided to limit this section to only a small number of specific types of supplies and equipment (such as drugs) for which we proposed to collect costs separately. We believe that the data collected through the data collection instrument may point to opportunities for additional refinement in this section in future years of data collection. For example, rather than collect information on all drugs in aggregate, reporting by category of drug or even for individual drugs may provide useful information. Still, given the fact that information on ground ambulance costs is limited, we believe the appropriate first step is to collect higher-level cost information. We also agree with the commenters that items such as nebulizers should be considered non-capital equipment as they are typically a single usage device when used by ground ambulance providers and suppliers. In the process of developing the survey, we heard from many organizations about the increasing cost of medications and as a result, we requested these items to be reported separately. We recognize that some organizations may not be able to separate their drug costs from other medical consumables, so this question is optional on the survey.

After consideration of the comments, we removed the example of nebulizers from the capital equipment section.

(v.) Collecting Data on Other Costs

In addition to core costs for ambulance providers and suppliers that are associated with labor, vehicles, facilities, and equipment or supplies, ground ambulance organizations have indicated that these entities incur costs associated with contracted services (for example, for billing, vehicle maintenance, accounting, dispatch or call center services, facilities maintenance, and IT support), as well as other miscellaneous costs (for example, administrative expenses, fees and taxes) to support ground ambulance services.

In the proposed rule, we considered including contracted services as part of the labor section, since many of the contracted services related to costs that would otherwise be labor-related if the tasks were performed by employed staff. However, we were concerned that ground ambulance organizations might report this information in multiple data collection instrument sections (for example, both labor and miscellaneous costs). As a result, we separated contracted services into their own categories. While we considered allowing respondents to report in the aggregate any other miscellaneous costs associated with ground ambulance services because we stated we believed this approach may be less burdensome for organizations that track miscellaneous costs in aggregate, we stated we believed this would introduce a large amount of reporting bias and inconsistency in reporting across organizations. In the proposed rule, we made several proposals related to reporting contracted services and miscellaneous costs as described below.

Reporting Contracted Services

For contracted services, we proposed that respondents indicate whether their organization utilizes contracted services to support a variety of tasks (Section 11, question 1), the associated total annual cost for these services, and the percentage of costs attributable to ground ambulance services. The data collection instrument provided instructions to ensure that respondents do not report on contracted costs multiple times.

Reporting of Miscellaneous Costs

For other miscellaneous costs not otherwise captured in prior sections of the data collection instrument, we proposed that respondents be able to report additional costs first using an extensive list of other potential cost categories (Section 11, question 2) and then use write-in fields if necessary. We stated that providing a pre-populated check list would help ensure the consistency and completeness of reporting across respondents.

Allocation of Miscellaneous Shared Costs

Information from ground ambulance organizations indicates that there are a number of miscellaneous costs associated with the overall operation of organizations that are shared across services. To account for these shared costs, we proposed that respondents report an allocation factor for each contracted service, (Section 11, question 1), as well as for each reported miscellaneous expense (Section 11, questions 3–4) as described in the data collection instrument. We considered the alternative of asking for an overall share of miscellaneous costs associated with ground ambulance services or utilizing information gathered about the share of ground ambulance responses versus total responses to determine an overall allocation factor. We stated that while this would present less burden on respondents, the share of miscellaneous costs and share of contracted services varies widely across organizations with shared services.

We received comments on collecting data on other costs. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed data elements for other costs, but as noted with regard to labor, they requested clarification as to the allocation of medical director fees to ensure there is no double-counting between the two sections.

Several commenters stated that Section 11, Question 3 (advertising expenses) of the data collection instrument directs respondents to provide information on a variety of general and miscellaneous costs. They stated they believe CMS should clarify what is meant by the ''Advertising'' category of expenses because it is unclear whether this is generic advertising to the public or if this would be inclusive of advertising conducted in order to recruit volunteer personnel. Additionally, they thought CMS should clarify which advertising expenses this includes (print, television, radio, online/social media, trade show exhibitions, promotional items such as shirts and stickers, etc.).

Another commenter suggested that CMS collect information about unpaid transports (excluding charitable care) and/or uncompensated health care services when no transport is involved. They stated that they recognize that Section 5 in the data collection instrument asks about the volume of paid transports. They stated that it is not clear that information about the actual costs associated with unpaid transports could be determined through the other questions at this time but that this information is essential to understand how the limitations in the current Medicare benefit have a negative impact on overall Medicare costs. They also stated that this information would also help policy-makers assess how unpaid services could be addressed in the future. They stated that they believe that this information should be distinguished from bad debt or charitable care, because the former implies the inability to collect coinsurance amounts, while the latter indicates services provided to those without insurance or funds to pay for the services. This unpaid category would be focused on transports or services provided to patients with insurance, but for which the insurance company refuses to pay.

One commenter suggested that costs for franchise fees needed to be collected in the survey because franchise fees are costs some organizations pay local governments to operate within the jurisdiction. The same commenter advised that dispatch costs would be difficult to capture for rural organizations because dispatch services are generally run by a central entity such as county government. Finally, one commenter requested clarification on what was included in 'total costs' and 'total revenues' as to whether this included total costs and revenues from organizations with shared services.

Response: As noted in our response to comments in the labor section, we are moving the reporting of contracted medical director services to the labor section to avoid potential confusion and double-counting. More generally, the proposed data collection instrument included an instruction in the contracted labor section to not report funds that had already been reported elsewhere in the survey. We agree with the comment suggesting clarifications to the definition of advertising. While the proposed data collection instrument collects some information relevant to uncompensated care, we did not intend to directly collect respondents' estimates of uncompensated care. The data collection instrument does collect information on the total costs borne by the ground ambulance organization, including costs related to transports for which no or partial payment is received. The data collection instrument also collects information on the total number of transports for which payment is received versus total transports.

In response to the suggestion to add a question to collect information on franchise fees, we wanted to highlight that this data item is already being collected in the section on other costs, which reads as follows: ''Fees paid to local jurisdictions required as condition of providing ground ambulance service.''

We intended the total costs and total revenues to incorporate the full totals for each question. This means that for organizations with shared services, they would report their full operating and capital costs, and revenues, even for the portions of their business unrelated to ground ambulance service. For example, a fire department also operating an ambulance service would answer this question with their total cost and total revenue across the whole organization. For organizations without shared services, their total costs will match those reported in the data collection instrument. For organizations with shared services, their total costs will be higher than those reported in the data collection instrument.

After consideration of the comments, we clarified the definition of advertising to include any type of advertising (even for recruiting purposes) in any medium (print, radio, internet, etc.). We also added additional clarification to the questions for total costs and total revenues.

d. Data Collection on Revenue

Section 1834(l)(17)(A) of the Act requires the development of a data collection system to collect revenue information for ground ambulance provider and suppliers. Payments from Medicare and other health care payers are important components of total revenue for some ambulance providers and suppliers. Most ambulance providers and suppliers also have other sources of revenue in addition to payments for billed services. Based on review of existing literature and discussions with ground ambulance organizations, these primary sources of revenue include, but are not limited to: Patient out-of-pocket payments; direct public financing of fire, EMS, or other agencies; subsidies, grants, and other revenue from local, state, or federal government sources; revenue from providing services under contract; and fundraising and donations. In the proposed rule we stated that we view total revenue as the sum of payments from health care payers and all other sources of revenue, including those listed above.

We stated that while collecting information on total revenue is essential to understanding variations in how EMS services are financed across the country, this information is not collected by Medicare or by any other entity of which we are aware. Similar to other sections of the data collection instrument, we stated that we also considered what level of data to request in this section. We proposed to ask for total revenue in aggregate (Section 13, question 1) and total revenue from paid ground ambulance transports for Medicare and, if possible, broken down by payer category for other payers (Section 13, questions 2–5). We proposed this level of detail because we believe understanding payer mix would be helpful to assess Medicare's contributions to total revenue. We stated that based on information provided by ambulance providers and suppliers, there is variation in how patient-paid amounts were recorded in ambulance billing systems. We proposed to ask respondents whether revenue by payer includes corresponding patient cost sharing or whether cost-sharing amounts are included in a self-pay category. For other revenue (for example, contracts from facilities and membership fees (such as those associated with community members that enroll in ambulance clubs), we proposed to request information on additional revenue in predetermined categories and using write-in fields if necessary (Section 13, question 5).

Allocation of Shared Revenues. Ground ambulance organizations vary widely in the types of other revenue sources (as noted in Section 13, question 6) they receive and their share of allocated costs. For this reason, we proposed to have respondents report the share of revenue for each category that is attributable to ground ambulance services (Section 13). Similar to miscellaneous costs, we considered the alternative of asking for an overall share of other revenue sources associated with ground ambulance services or utilizing information gathered about the share of ground ambulance responses versus total responses to determine an overall allocation factor. While this would present less burden on respondents, we stated that we did not believe it would adequately capture the revenue only associated with ground ambulance services, especially for organization with shared services.

To collect information on uncompensated care, including charity care and bad debt, we proposed to collect information on both total and paid transports. We stated these two measures of volume can be used to provide insight into the share of transports that are not paid. The data collection instrument broadly collects information on total costs (including costs incurred in furnishing services that are ultimately paid and not paid) and total transports (again including transports that are both paid and not paid). We stated that the collected data could be used to estimate per-transport costs that can be estimated by dividing total costs by total transports, so we do not believe it is necessary to directly collect information on uncompensated care in the revenue section of the data collection instrument.

We invited comments on collecting revenue. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the collection of ground ambulance revenue from different types of payers, as well as the collection of other sources of revenue. These commenters asked that CMS divide Medicaid revenue by traditional Medicaid and Medicaid managed care, similar to the separate lines for Medicare fee-for-service and Medicare Advantage and recommend that CMS define the term ''ambulance club,'' which they stated is not a standard term.

Several commenters asked CMS to add a revenue category to Section 13, Question 5 in the data collection instrument to collect in-kind contributions (including labor, supplies, medications, etc.) provided by another agency which responds to calls for emergency service in conjunction with the ground ambulance organization completing the data collection instrument. Commenters would like respondents to select yes or no, enter the dollar amount, and enter a percentage. They stated that fire departments often provide EMS care to patients, including at the ALS level, even when another agency provides the actual ground transportation services to a patient and when this occurs, the fire department's ALS personnel often continue providing patient care inside the third-party ambulance during transportation to the hospital. They stated that this continuation of patient care by fire department personnel constitutes a significant savings to the third-party transportation company as they do not incur the costs associated with the fire department employee(s) such as salary, benefits, and insurance. They also stated that in many cases, the fire department never receives reimbursement for these costs by the third-party ground ambulance agency. They stated that since the data collection instrument only will apply to Medicare-enrolled ground ambulance agencies that they believe that the data collection instrument should count these services as in-kind contributions to the third-party ambulance agency. Commenters further stated that ground agencies selected for sampling by CMS each year can easily gain this information by requesting it from the agencies which commonly respond to calls for emergency service with the third-party ground ambulance agency.

Several commenters stated that Section 11, Question 5 seeks information from respondents on several revenue categories which may apply to an ambulance supplier or provider. They stated that since the goal of the data collection instrument is to assess the adequacy of CMS' reimbursements for the cost of providing patient care, they believed that the inclusion of tax revenue for public agencies could lead to the inclusion of unrelated data. They stated that operating revenue that is derived from taxation and provided to public agencies represents the level of service expected by a community but is not expected to be a dollar-for-dollar coverage of patient care costs and that these funds should supplement, not supplant, CMS' reimbursements to public agencies for the care that they provide to Medicare beneficiaries. They also stated that they believed that tax-derived subsidies should be reported by respondents when these funds are included in a larger contract between a local government and a private entity. They stated that in these cases, these subsidies are intertwined with the overall structure and terms of the contract but that they do support the requirement for respondents to report when revenue is received by any agency (public or private) through an EMS-specific tax and as a result, they recommend that CMS adopt changes to Section 13, question 5.

Another commenter suggested that donations to organizations that support volunteers should be considered in the revenue section. This same commenter also requested clarification as to whether patient self-pay includes the uninsured or uncovered transports.

Response: We agree that it would be informative to distinguish between traditional FFS Medicaid and Medicaid managed care revenue and will add that option to the instrument. We use the term 'ambulance club' to describe a membership organization where local residents pay a regular fee for ambulance service not provided by their local governments. We do not agree with the commenter suggesting to collect information on the in-kind subsidies provided by other, non-transporting agencies who assist the reporting organization at the scene or while transporting patients. We believe this additional question will add substantial burden for organizations who must collect it, as this requires valuing the other organization's labor, supplies, vehicles, facilities, etc., and this information will be captured in the cost sections if there is a contract between the organizations for reimbursement.

The data collection instrument is designed to capture the costs of operating a ground ambulance service, consistent with our statutory requirements and we do not believe that including donations to other organizations would be appropriate to include. Donations, payment, or benefits made by other entities that support staff or other services that are out of scope for this data collection are also out of scope when reporting revenue. The patient self-pay revenue section is intended to capture payments patients made to the ambulance organization for a transport that was covered or not covered by their health insurer.

We are required to collect information on revenue received by ground ambulance organizations. Therefore, we do not agree that tax revenue for public agencies should be excluded from the data collection instrument because omitting questions related to this source

of revenue from that data collection instrument would result in an incomplete picture of revenue across different types of ground ambulance organizations. The data collection instrument collects information separately on tax revenue for public agencies and from contracts between local governments and ground ambulance organizations.

After consideration of the comments, we clarified the meaning of an ambulance club and added an option to separately report Medicaid Managed care revenue. We also added an option to separately report contract revenue from local governments, as well as tax revenue from local governments, and clarified that self-pay refers to non-covered transports.

After consideration of the comments regarding the data collection instrument, we are finalizing our proposals regarding the format, scope, costs and revenue with several modifications or clarifications as described in the sections above.

5. Final Policies for Sampling

Section 1834(l)(17)(B)(i) of the Act requires that CMS identify the ground ambulance providers and suppliers organizations that would be required to submit information under the data collection system, including the representative sample. Section 1834(l)(17)(B)(ii)(II) of the Act requires the representative sample must be representative of the different types of providers and suppliers of ground ambulance services (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas). Under section 1834(l)(17)(B)(ii)(III) of the Act, the Secretary cannot include an individual ambulance provider and supplier in 2 consecutive years, to the extent practicable. In the proposed rule, we stated that in addition to meeting the requirements set forth in the statute, including developing a reprentative sample, our proposals around sampling aim to balance our need for statistical precision with reporting burden. We also stated that our we developed our proposals with the intention of obtaining statistical precision with the least amount of reporting burden.

Eligible Organizations. In the proposed rule, we stated that a sampling frame drawing on all ground ambulance organizations in the United States and its territories that provide ground ambulance services (that is, not just those enrolled in Medicare or billing Medicare in a given year) may be of interest conceptually, but that we have not identified a data source listing all ambulance providers and suppliers that could be used as the source for a broader sampling frame. Since sections 1834(l)(17)(A) of the Act requires the Secretary to collect cost, revenue, and utilization information from providers of services and suppliers of ground ambulance services (which are Medicare specific terms with specific meaning) with the purpose of determining the adequacy of payment rates and section 1834(l)(17)(D) of the Act requires the Secretary to reduce payments to ground ambulance organizations that do not sufficiently report, we stated we believe that the intent of the statute is to collect information under the data collection system from ground ambulance organizations that bill Medicare. Therefore, we proposed to sample ground ambulance organizations that are enrolled in Medicare and that billed for at least one Medicare ambulance transport in the most recent year for which we have a full year of claims data prior to sampling. Since ground ambulance organizations have a full year to submit their claims to Medicare after the date of service, claims data for a calendar year are generally not considered complete until the end of the following calendar year. We stated that as a result, we would use 2017 Medicare claims and enrollment data to determine the sample for the 2020 data collection period because 2018 Medicare claims data could not be considered complete in late 2019 when the sample for the 2020 data collection period would be selected.

Sampling at the NPI level: Section 1834(l)(17) of the Act prohibits, to the extent practicable, sampling the same ambulance provider or supplier in 2 consecutive years. Although we stated we considered sampling at a broader parent organization level for those that bill Medicare under more than one NPI, we stated we found it was difficult to tease out of the Medicare enrollment data all the complexities of the business relationships and identify all NPIs that may be affiliated with the same parent organization. Therefore, we proposed to select the sample at the NPI level and to include the specific NPI selected to report information. Furthermore, we proposed to collect the name of the ground ambulance organization and the name and contact information of the person responsible for completing the data collection instrument for the purposes of confirming that the data submitted aligns with the intended NPI (Section 2, questions 3 and 4).

Organizations using volunteer labor: Some stakeholders have suggested that ground ambulance organizations relying on volunteer labor above a certain threshold (for example, more than 10 percent of volunteer labor) should be exempt from sampling. Others have suggested that ground ambulance organizations using volunteer labor should not be excluded because those organizations that use volunteer labor are likely to be smaller and that a large share of ambulance suppliers (particilarly those in rural and super rural areas) would be exempt from sampling, and therefore, our sample would not be representative as required by section 1834(l)(17)(B)(ii) of the Act. We acknowledged that analysis of the data may require additional steps to combine data submitted from ground ambulance organzations that do and do not rely on volunteers since reported labor costs would be significantly lower for ground ambulance organizations that use volunteer labor compared to those that do not. We stated that ground ambulance organizations that use volunteer labor might have some costs related to their volunteer labor, such as stipends, but may not have others, such as an hourly wage. Therefore, we proposed to collect information on paid and unpaid volunteer hours during a typical week using the same EMT/response staff categories used elsewhere in the data collection instrument. We stated we believed reported hours could be converted to market rates using data from other sources, such as the Bureau of Labor Statistics' wage data. Ambulance providers and supplies that rely on volunteer labor reported that it is becoming increasingly difficult to find volunteers and they are having to hire paid staff in their place, especially for the more costly labor categories, such as paramedics. Therefore, we proposed that ambulance providers and suppliers that use any amount of volunteer labor be included in sampling. We invited comments as to whether organanizations that rely on volunteer labor should be exempt from sampling.

Sampling file. We proposed several organizational characteristics for the specific strata (volume of Medicare billed transports, service area population density, ownership, provider versus supplier status, and the share of transports that are non-emergency) that we stated could be obtained from available Medicare data. We proposed to develop sampling files using the most recent full year of data available. For the first sample notified in 2019 and

reporting in 2020, we proposed to use 2017 claims and enrollment data. Another alternative we considered was using 2018 data, however we did not propose this because such data may not be complete for all 2018 service dates at the time the sample for the initial year of data reporting is selected. We invited comments on our proposal to use the most recent full year of available Medicare data for sampling purposes, as described above.

Implications of historical sampling files. In the proposed rule we stated that we expect there may be instances in which some ground ambulance organizations that were in operation at the time they were selected for the sample may cease operations by the time data reporting begins and that we expect that some new ground ambulance organizations would start operating between the time the sample was created and when reporting begins. Since we proposed to collect a full 12 continous months of data, these organizations would not have the data we proposed to collect. Therefore, we proposed that ground ambulance providers and suppliers organizations selected for the sample that were not operating for the full 12 continuous months of the data collection period would be exempt from reporting for the applicable data collection period; however, for newer ground ambulance organizations, they would be eligible for sampling and reporting in future years when they have a full continuous 12 months of data.

We stated that we believed the above scenerios are inevitable given the significant amount of time between sampling and data reporting and invited comments on our approach regarding exempting ground ambulance organizations who do not have a full 12-month continuous period of data.

Sampling rate: We proposed that 25 percent of ground ambulance organizations be sampled from all strata (as described below) in each of the first 4 years of reporting without replacement; that is, if an organization is sampled in Year 1, it would not be eligible for sampling again in the subsequent 3 years of data collection. We proposed a 25 percent sampling rate because we stated if a lower sampling rate is used, estimates of cost, revenue, and utilization from the data collected via the data collection instrument for subgroups of ground ambulance suppliers will be of inadequate precision as described in the following section. We stated that our analyses illustrated that using a 50 percent sampling rate would yield only marginal gains in precision over a sampling NPIs at a 25 percent rate while doubling the response burden. We stated that in our view, these gains are not sufficient to merit the increased burden that would be imposed by implementing a higher sampling rate. We stated that our proposal was informed by analyses regarding the alternative sampling rates in Chapter 7 of the CAMH report. We invited comments on the sampling rate of 25 percent each year.

We also proposed to notify ground ambulance organizations that have been selected for the representative sample by listing such ground ambulance organizations on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html* and provide written notification to each selected ground ambulance organization via email or U.S. mail. We stated that notification on the CMS website would be provided at least 30 days prior to the time the selected ambulance organization would will be required to begin collecting data. For purposes of CY 2020, we stated that we would post such information on the website when the CY 2020 PFS final rule is issued. We also proposed to codify the representative sample requirements in § 414.626(c).

Approach for Sampling: In the proposed rule, we considered several alternatives for developing a stratified sampling approach to facilitate data collection from specific types of ground ambulance oragnizations. Section 1834(l)(17)(B)(ii)(II) of the Act requires that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organization and the geographic locations in which ground ambulance services are funished (such as urban, rural, and low population density areas). One approach we considered was sampling ground ambulance organizations in proportion to their volume of Medicare-billed ground ambulance services. Under this approach, we stated that organizations with more billed Medicare ground ambulance transports would be more likely to be sampled than organizations with fewer billed Medicare ground ambulance transports. The analysis of our 2016 data described in the CAMH report shows that a small number of ground ambulance organizations provided a large share of total Medicare transports. We stated that the top 10 percent of ground ambulance organizations by volume accounted for nearly 70 percent of total Medicare ground ambulance transports and the bottom 50 percent of ambulance providers and suppliers by volume accounted for only 3 percent of total Medicare ground ambulance transports. Under this approach, we stated that the ambulance providers and suppliers in the top 10 percent by volume would be much more likely to be sampled compared to those in the bottom 50 percent by volume. We also stated that while this approach would efficiently collect data on the majority of Medicare ground ambulance transports, we do not believe that this approach would comport with the requirements in section 1834(l)(17)(B)(ii)(II) of the Act to develop a representative sample of ground ambulance organizations based on the characteristics (such as ownership and geographic location) of ambulance providers and suppliers. Therefore, we stated that we do not believe that data we would be collecting using this approach would meet the requirements in section 1834(l)(17)(B)(ii)(II) of the Act.

Other alternatives for a sampling methodology we considered included simple and stratified random samples of ground ambulance organizations. We stated a simple random sample would include a fixed share of all ground ambulance organizations, regardless of any differences in characterstics, in each year's sample. Unlike sampling in proportion to Medicare-billed ground ambulance services, we stated a simple random sample by definition provides a representative sample. A stratified random sample first stratifies all ground ambulance organizations based on selected characteristics and then a sample is seleced at random from the strata. We stated the rate at which these organizations are sampled would be the same for organizations in the same stratum; however, that the sampling rate may vary across strata. So long as the sampling rate is not zero within any stratum and so long as appropriate weighting adjustments are used, we stated the sample would be considered representative.

As discussed in the proposed rule, stratified random sampling has several advantages in that it is easy to implement and it meets the requirement that the sample be representative and it also can be used to target sampling of ambulance organziations with specific characteristics, such as ownership and geographic location, to specifically meet the requirements in section 1834(l)(17)(B)(ii)(II) of the Act that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of

a government organization and the geographic locations in which ground ambulance services are funished (such as urban, rural, and low population density areas). We stated that it is also possible to oversample from less prevelant strata using this approach in order to facilitate more precise estimates for certain groups or comparisons between subgroups. Furthermore, unlike a simple random sample, we stated the flexibility to vary sampling rates across strata allows the ability to account for anticipated and unanticipated rates of nonresponse.

We stated that we believe that use of a stratified random sample would comport with the statutory requirements. Therefore, we proposed a stratified random sample approach. Specifically, we proposed to sample from each strata at the same rate (25 percent, as described above). We stated we believe that data collected from a sample of this type can be adjusted via statistical weighting to be representative of all ground ambulance organizations billing Medicare for ground ambulance services even if response rates vary across the characteristics used for stratification.

For the purposes of estimating the number of responses from the sampled ground ambulance organizations, we stated we assumed that all ground ambulance providers and suppliers organizations sampled will report, because: (1) Reporting is a requirement; (2) there is a 10 percent payment reduction for failure to sufficiently report; and (3) we believed every ground ambulance organization would want its data accounted for in the evaluation of the extent to which reported costs relate to payment rates.

Variables for Stratification: Section 1834(l)(17)(B)(ii)(II) of the Act requires that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organization, and the geographic locations in which ground ambulance services are funished (such as urban, rural, and low population density areas). We proposed a stratified sampling approach under which we would first sample based on a set of characericistcs of ground ambulance organizations that are described below (that is, strata) and then assess response rates based on those characteristics. Based on our analysis of information provided by ground ambulance organizations, we stated we believed there are several important characteristics that vary among ground ambulance organizations that have implications for their costs and revenues and that could serve as strata for the purposes of sampling:

- *Provider versus supplier status.* The GAO (2012) [97] and HHS (2015) [98] reports found much higher per-transport costs for ambulance providers than those of ambulance suppliers. We stated this suggests that the ground ambulance cost structures for ambulance providers and suppliers are fundamentally different.
- *Service area population density.* Ground ambulance organizations operate in urban, rural, and super-rural settings. As described in the CAMH report, rural and super-rural organizations tend to be smaller, transport patients at greater distances, are more likely to be government owned, and rely more heavily on volunteer labor. We stated the population density of the area in which a ground ambulance organization is operating is expected to affect costs and revenues in a number of ways. Organizations serving rural and super-rural areas generally are likely to face lower demand for services, and thus, deliver a smaller number of transports. In addition, in rural and super-rural areas the average distance traveled per transport tends to be greater. We further stated that payment rates will also differentially impact revenue by population density because the Medicare AFS accounts for mileage and, in addition, rural and super-rural providers and suppliers receive higher temporary add-on payments.
- *Volume of transports.* If there are economies of scale, organizations providing a larger volume of services typically would face lower per-transport costs. We stated our analysis found the majority of ground ambulance organizations have a low volume of transports, but there are a small number of organizations with a very high volume of transports. Additionally we stated that suppliers providing a large volume of transports are more likely to be for-profit organizations.
- *Ownership.* For-profit (non-government), non-profit (non-government), and government ground ambulance organizations have different business models and mixes of services, leading to different costs. We stated conceptually, for-profit organizations maximize profit and operate only in markets and service lines with positive margins and that non-profit and government ground ambulance organizations more broadly provide emergency service to communities and may be organized and operated in a way that does not maximize profits. The 2012 GAO report found ground ambulance organizations with more limited government support are more likely to have incentives to keep costs lower. They found that for each 2 percent decline in the average length of government subsidy there was a 2 percent decline in the average cost per transport. As a result, we stated we expect that costs will differ based on ownership.
- *Types of services provided.* One key distinction in the types of services provided is between emergency transports and non-emergency (for example, scheduled or inter-facility) transports. We stated that for-profit suppliers are more likely than others to specialize in non-emergency scheduled transports. We stated that another key distinction is between the level of service provided (for example BLS versus ALS).
- *Staffing.* The level of staff training (for example, EMTs versus paramedics) and the number of staff deployed is driven in part by the type and volume of calls, the availability and proximity of the nearest providers, and resources available in that community. We stated that some suppliers use static staffing models that use set staff schedules, whereas others use a dynamic, or flexible, staffing model that calls upon staff if there is a surge in demand.
- *Use of volunteer labor.* Volunteer labor tends to be more common among small, government-based ambulance suppliers operating in rural and super-rural settings.
- *Response times.* In many cases, response times are related to the population density of the area in which they operate, with rural areas having response times more than double those of urban areas. We stated that rural and super-rural ambulance providers and suppliers generally travel greater distances to get to patients and transport them to a hospital or the nearest appropriate facility. We also stated that variation in response times within urban areas might also occur, for example if there is significant emergency department crowding, or in extreme cases diversion that requires the ambulance to travel further to another hospital or wait with the patient until a bed is available and that this extra time affects the availability of the ambulance and the staff for subsequent trips, potentially increasing response times.

We stated we were not aware of any existing data source that lists all ground

[97] This report is available at *https://www.gao.gov/assets/650/649018.pdf.*

[98] This report is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf.*

ambulance organzations or one that encompasses all the characteristics that impact costs and revenues described above. We stated that Medicare claims and enrollment data is the only source of data for which we were aware that has all the providers and suppliers that bill Medicare in a given year. We stated that several of the organizational characteristics we discuss above (including provider versus supplier status, ownership, service area population density, Medicare billed transport volume, and type of services provided) are available from Medicare data while others, such as the use of volunteer labor, staffing model, and response times are not.

We proposed to stratify the sample based on provider versus supplier status, ownership (for-profit, non-profit, and government), service area population density (transports originating in primarily urban, rural, and super rural zip codes), and Medicare billed transport volume categories. Based on our analysis of the number and distribution of ground ambulance organizations' transports in 2016, we proposed volume categories of 1 to 200, 201 to 800, 801 to 2500, and 2501 or more paid Medicare transports. The volume categories aim to divide ground ambulance organizations into roughly similar-sized groups, while separating ground ambulance organizations with very high volume (that is, greater than 2500 Medicare transports per year) into a separate category. We stated we would expect that these highest-volume ground ambulance organizations may face different costs than lower-volume organizations due to economies of scale.

We proposed to focus on these four characteristics due to data availability, and our analyses that show these to be key defining characteristics of ground ambulance organizations (which are also described in the CAMH report). We stated that service area population density and Medicare billed transport volume have a direct impact on ground ambulance revenue, which is one of the categories of data that we are required to collect by section 1834(l)(17)(A) of the Act. We stated that through Medicare claims and enrollment data, we believe we have enough information to stratify ground ambulance organizations on these four characteristics. This stratification approach results in 36 groupings of ground ambulance suppliers (defined by combinations of the three ownership categories, three service area population density categories, and four Medicare billed transport volume categories) and the same number of groupings for ambulance providers.

In some of these groupings, there are only a handful of ground ambulance organizations providing ground ambulance services with a specific set of the four characteristics. We stated this could result in situations where few or no ground ambulance organizations with the specific set of characteristics were sampled. To minimize this risk and avoid situations where we are sampling from strata that contain only a few ambulance providers and suppliers in the entire population, we proposed to stratify ground ambulance providers, which account for only 6 percent of ground ambulance organizations combined, based on service area population density only. We proposed to use this characteristic to stratify providers rather than another characteristic because section 1834(l)(17)(A) of the Act specifically requires the Secretary to develop a data collection system to collect information on ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in section 1834(l)(12) of the Act (super rural areas).

We also proposed to collapse the two highest Medicare ground ambulance transport volume categories (801–2500 and 2501 and more transports) into a single category (801 and more transports) for for-profit ground ambulance suppliers that primarily service super-rural areas due to the small number of ground ambulance organizations in these two volume categories. We stated the proposed sampling rate of 25 percent aims to meet a threshold that will provide an adequate degree of precision for estimates within each strata subgroup (that is, provider versus supplier status, ownership (for-profit, non-profit, and government), service area population density (transports originating in primarily urban, rural, and super rural zip codes), and Medicare billed transport volume categories). The specific threshold is 200 expected responses in each subgroup. This number of expected responses will ensure that small to medium differences in means between groups (that is, affect size) can be detected.

We stated that a 25 percent sampling rate is expected to result in more than 200 responses in each subgroup except for ground ambulance providers (where we expect 153 responses with a 25 percent sampling rate) and that a 25 percent sampling rate will result in more than 200 expected responses for other organizations not represented in the strata, including organizations providing primarily non-emergency transports and transports to and from dialysis facilities. We stated that we also expect that a 25 percent sampling rate will result in more than 200 responses for organizations that rely primarily on volunteer labor, as well as for those who do not.

We invited comments on all our proposals for sampling including our proposals on eligible organizations, methods for sampling, sampling at the NPI level, sampling of organizations using volunteer labor, sampling files, and sampling rates. We also invited comments on our proposals to collect data from ground ambulance organizations that bill Medicare, and the use of a stratified random sample.

We received comments on our proposals for sampling as described in this section. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally very supportive of our proposals and agreed that the data collection effort must cover ground ambulance organizations of all types (government, for-profit, not-for-profit, provider-based, and volunteer) regardless of size and service area (urban, rural and super rural). They stated that all ground ambulance organizations must be represented in the samples to allow for stakeholders and policy-makers to understand the true cost of providing ambulance services in the geographically diverse areas of the country. Some commenters also believe that this information is important to support the permanent inclusion of the urban, rural, and super-rural add-ons into the AFS payment. Commenters noted that while it may be more difficult for some smaller or rural/super-rural ground ambulance organizations to provide such data, their data are essential for policy-makers to evaluate the ambulance benefit in its entirety.

One commenter stated that, while they believe it is important for organizations that rely on volunteer labor to be included in the sampling, they encourage CMS to consider exempting from sampling ground ambulance organizations with very low volumes of Medicare-billed transports where the payment reduction for not reporting data would be less than the cost of reporting data. One commenter advocated for excluding organizations with workforces consisting of 50 percent or more volunteer labor because of the administrative burden associated with reporting. Another commenter expressed concern that the penalties for not reporting would endanger the

financial health for small, rural ambulance organizations.

Response: We recognize that there may be some ground ambulance organizations that have limited resources that affect their ability to report the required information, and that for these ground ambulance organizations, a 10 percent payment reduction in Medicare payments could result in significant financial hardship. However, we believe that it is critical that ground ambulance organizations of all types submit data so that we can all understand better the costs of furnishing ground ambulance services, including ground ambulance services furnished in very low-volume or in rural and super-rural areas. This is particularly important because several payment policies such as current add-on payments specifically apply to ground ambulance services in rural and super-rural areas, and therefore, we do not agree that small ground ambulance organizations should be excluded from sampling. While some very low volume ground ambulance organizations may conclude that the payment reduction will be less than the estimated costs of collecting and reporting data, we believe it is important to offer all ground ambulance organizations the opportunity to submit data and participate in this important national data collection activity. If we were to systematically exclude any category of ground ambulance organizations, for example organizations with very low volumes of Medicare-billed ground ambulance services, there would be gaps in our understanding of important segments of ground ambulance organizations and their role in the country's emergency response system. We note that section 1834(l)(17)(A)(D)(iii) of the Act authorizes the Secretary to exempt a ground ambulance provider or supplier from the 10 percent payment reduction for an applicable period in the event of significant hardship, such as bankruptcy, which is discussed in detail below in this rule.

Comment: Many commenters stated that they support a stratified sampling approach and believe the proposed approach should allow the end users of the data to ensure a representative sample and facilitate analysis of subgroups of ground ambulance organizations, but would have preferred that CMS first obtain information about organization type, utilization patterns, and other relevant organizational characteristics to support a stratified random sample before collecting cost, revenue and other data. They believed CMS would have been better positioned to ensure that, when it fields the data collection instrument it is obtaining a representative sample of all types, sizes, and geographic distribution of ground ambulance services if they had first collected organizational data from all ground ambulance organizations. Commenters asked that CMS work closely with stakeholders during the first years of the system to identify and resolve any problems that arise. They also stated that prior research echoed the need for a stratified sample due to variation in the level of transport costs resulting from various business models present in the industry.

Response: As we have stated above, we do not believe that it is necessary to first collect only organizational characteristic data from all ground ambulance organizations prior to collecting cost, revenue and utilization data. We believe that CMS' claims and enrollment data are sufficient for the purposes of selecting stratified samples of ground ambulance organizations.

Comment: Many commenters stated that they agree that selecting 25 percent of ground ambulance services (defined at the National Provider Identifier level) is appropriate for each of the 4 years of the system. They quoted prior research that has indicated that a sample of approximately 15–25 percent of the ambulance industry should be sufficient to ensure cost data are representative of the industry overall and for subgroups of ground ambulance organizations, reliable in establishing ambulance payment rates, and a significant improvement on the data used to establish the current payment rates. They also stated that prior efforts to sample ambulance cost data have generated varying results and in order to generate a representative sample CMS needs a larger sample than has been conducted in the past. They stated that business models of ambulance providers and suppliers vary in terms of their service areas, types of services, and most importantly their volume of transports. To account for this variation, the commenters recommended that the sample should support analysis for 14 different subgroups of ground ambulance organizations: Super-rural (majority of transport pick-ups in super rural zip codes), rural (majority of transport pick-ups in rural zip codes), urban (majority of transport pick-ups in urban zip codes), for-profit, not-for-profit, government entity (not including fire/public safety), volunteer-based, hospital-based, fire/public safety-based, low transport volume (less than 600 transports per year), medium transport volume (600 to 5000 transports per year), high transport volume (more than 5000 transports per year, Advanced Life Support (ALS) transport-focused (greater the 90 percent of transports are ALS), and Basic Life Support (BLS) transport-focused (greater than 90 percent of transports are BLS). These commenters stated that it may be necessary to sample 100 to 200 of each type of providers and suppliers. They stated that they believe that response rates are not likely to be a problem in collecting the data due to the reduction Congress has tied to non-responders.

Response: Our proposal to sample 25 percent of all ground ambulance organizations in each of the 4 years is based on our analysis which shows that this approach will ensure we have enough data for analysis and that the sample is a representative of all ground ambulance organizations in each of the years of data collection. We believe that this approach is consistent with the statutory requirements regarding data collection. As we noted in the proposed rule, we believe those analyzing the data will want to calculate estimates for subgroups of the ground ambulance organizations in the sample, for instance ground ambulance providers operating primarily in super-rural areas that are government owned or for profit ground ambulance providers operating in urban areas. We also noted that we believe that 200 responses per subgroup will be necessary in order to calculate estimates of sufficient precision within different subgroups of ambulance organizations. Furthermore, we noted that a sample of 25 percent of ground ambulance organizations will result in data collected from more than 200 ground ambulance organizations in nearly all of the subgroups that we noted may be of interest to those analyzing the data. Lastly, we said that response rates lower than 25 percent would result in fewer than 200 sampled ground ambulance in additional subgroups of ground ambulance organizations and that estimates from data summarized from fewer than 200 respondents in a particular type or category will be less precise than necessary to determine the adequacy of payments.

Comment: One commenter suggested that CMS select a sample of respondents that is in proportion of their volume of Medicare-billed ambulance services. For example, if 94 percent of Medicare ground ambulance claims are submitted by independent ambulance suppliers, then ideally 94 percent of each year's survey sample would consist of independent ambulance suppliers. Similarly, the 50 percent of organizations that make up only 3 percent of Medicare ground ambulance claims would make up only 3 percent of

the sample. They also suggested that to allow MedPAC to produce the most accurate analysis for their Congressional report by the March 15, 2023, statutory deadline, MedPAC would need to receive data from a robust sample of ambulance organizations by March 2022. Therefore, they believe the first year's survey sample should be large enough to produce statistically reliable results using that year's data alone. In addition, they stated that all high-volume ambulance organizations (for example, the 10 percent of organizations that provide 70 percent of Medicare ground transports) should be surveyed within the first 2 years of data collection with 50 percent of these organizations surveyed in the first year and the other 50 percent surveyed in the second year.

Response: We do not agree that ground ambulance organizations should be sampled solely in proportion to their volume of Medicare ground ambulance service claims. While such an approach would collect information sooner from the small number of ground ambulance organizations that account for the majority of Medicare ground ambulance transports, it would shift the focus of the data collection effort almost entirely towards these large organizations at the expense of including smaller organizations. Our analysis indicates that the top 3 percent of organizations in terms of Medicare ground ambulance transport volume (all with more than 10,000 transports per year) account for 39 percent of total Medicare transports while the bottom 42 percent (all with fewer than 200 transports per year) account for only 2 percent of total Medicare transports. We believe that under our approach, each ground ambulance organization has an equal probability of being included in the sample. We also agree with other commenters that stressed the importance of a broad and inclusive approach to collecting data from all types of ground ambulance organizations, and sampling solely in proportion to volume would dramatically decrease the contributions of some types of ground ambulance organizations to the data collection effort.

We believe that the 25 percent sample proposed and supported by almost all commenters will yield sufficient data for analysis of the data after each year of data collection. While sampling at higher rates for some or all types of ground ambulance organizations in earlier years would result in additional data in the first year, we do not believe that the additional data is necessary to conduct an accurate analysis of the data. We disagree with the recommendation to sample ground ambulance organizations with the highest Medicare volume at higher rates in the initial years of data collection due to the concerns previously discussed about sampling solely in proportion to volume. We are also concerned that sampling larger ground ambulance organizations more heavily in the first 2 years of data collection will deter smaller ground ambulance from reporting because they will perceive that their data will not be used in the analysis.

After consideration of the comments, we are finalizing our sampling proposals to implement a 25 percent stratified sample in each of the first 4 years of data collection. We are also finalizing our proposal to codify the representative sample requirements at § 414.626(c).

6. Collecting and Reporting of Information Under the Data Collection System

For each data collection year, section 1834(l)(17)(C) of the Act requires ground ambulance organizations identified as part of the representative sample to submit information specified under the system, with respect to a period for the year (referred to as the ''data collection period''), in a form and manner and at a time (referred to as the ''data reporting period'') specified by the Secretary. In this section, we proposed to define the data collection period and the data reporting period. In determining when the data collection and reporting periods should fall, our objectives were to: (1) Allow selected ground ambulance organizations sufficient time to collect and report the required information; and (2) collect the data for analysis in the least burdensome manner.

We considered annual (that is, 12-month) data collection periods and shorter data collection periods (for example, a 6-month period). We proposed a 12-month data collection period because a shorter period could result in biased data due to seasonality in costs, revenue, or utilization among ground ambulance organizations.

As we stated previously, ambulance providers and suppliers constitute a diverse group of organizations with varied annual accounting practices. Accordingly, we proposed to define the data collection period as a continuous 12-month period of time, which is either the calendar year aligning with the data collection year, or when an organization uses another fiscal year for accounting purposes and the organization elects to collect and report data over this period rather than the calendar year, the 12-month period that is their fiscal year that begins during the data collection year. We proposed this data collection period based on feedback from ground ambulance organizations that stated that they prefer to collect data based on an annual accounting period (either calendar year or fiscal year) already used by the organization, and that requiring all organizations to report on the same 12-month period (for example, calendar year) could involve significant additional burden in terms of data collection and reporting. We believe that providing flexibility in collecting information under the data collection system would reduce the burden on ground ambulance organizations.

Therefore, we proposed that the first data collection period be January 1, 2020 through December 31, 2021, with organizations reporting on a calendar year basis collecting data from January 1, 2020 through December 31, 2021, and organizations reporting on a fiscal year basis collecting data over a continuous 12-month period of time from the start of the fiscal year beginning in calendar year 2020. Upon being notified that they are selected as part of the sample, ground ambulance organizations must notify CMS of their annual accounting period within 30 days according to the instructions in the notification letter, so that CMS is aware of when their data collection and data reporting periods would begin. We proposed that respondents would additionally confirm the data collection period when reporting data via the data collection instrument (section 2, question 5).

We also proposed that ground ambulance organizations would have up to 5 months to report to CMS (data reporting period) the data following the end of its 12-month data collection period. For example, if a ground ambulance organization is selected as part of the representative sample for the CY 2020 data collection year, and notifies CMS that its annual accounting period is based on a calendar year, the data collection period for this ground ambulance organization would begin on January 1, 2020 and end on December 31, 2020, and the data reporting period would be January 1, 2021 through May 31, 2021. A ground ambulance organization selected for CY 2020 that notifies CMS that its annual accounting period is based on a fiscal year basis with a fiscal year beginning on June 1, 2020 would have a data collection period from June 1, 2020 through May 31, 2021 and a data reporting period from June 1, 2021 through October 1, 2021. Since a 5-month reporting period is enough time for entities that file cost reports with Medicare to complete and submit their data, we believe it should

also provide adequate time for ground ambulance organizations to report information under the data collection system to CMS. This will allow providers and suppliers time to validate the information and certify the accuracy of their data required under the data collection before reporting it to CMS.

We proposed to codify the data collection and reporting requirements for selected ground organizations at § 414.626(b).

Tables 38 and 39 illustrate various examples of data collection periods and the data reporting periods that were proposed. Please note that an individual ground ambulance organization would only be selected to participate in one data collection and reporting period, and that the specific data collection and reporting period dates might vary for each organization and be different than the dates noted in Tables 38 and 39.

TABLE 38—EXAMPLE OF A DATA COLLECTION AND REPORTING PERIOD FOR A GROUND AMBULANCE ORGANIZATION WITH A CALENDAR YEAR ACCOUNTING PERIOD

Year	Data collection period	Data reporting period
1	01/01/2020–12/31/2020	01/01/2021–05/31/2021
2	01/01/2021–12/31/2021	01/01/2022–05/31/2022
3	01/01/2022–12/31/2022	01/01/2023–05/31/2023
4	01/01/2023–12/31/2023	01/01/2024–05/31/2024

TABLE 39—EXAMPLE OF A DATA COLLECTION AND REPORTING PERIOD FOR A GROUND AMBULANCE ORGANIZATION WITH AN ACCOUNTING PERIOD NOT BASED ON A CALENDAR YEAR

Year	Data collection period	Data reporting period
1	06/01/2020–05/31/2021	06/01/2021–10/31/2021
2	06/01/2021–05/31/2022	06/01/2022–10/31/2022
3	06/01/2022–05/31/2023	06/01/2023–10/31/2023
4	06/01/2023–05/31/2024	06/01/2024–10/31/2024

We invited comments on our proposal to use a 12-month data collection period. We also invited comments on our proposal to give sampled ground ambulances the flexibility to collect data on either a calendar year basis or on the basis of the ground ambulance organization's fiscal year. In addition, we invited comments on our proposal to allow a ground ambulance organization 5 months to report the data collected during data collection period to CMS through the data collection system. We stated that any ongoing collection of data after the initial 4-year period would be addressed in future rulemaking.

The following is a summary of the comments we received and our responses.

Comment: One commenter requested that we issue a technical correction to the proposed rule to correct the year for the first data collection period and the reporting calendar year.

Response: We thank the commenter for bringing this error to our attention and note that we inadvertently stated in one place in the proposed rule that the first data collection period would be January 1, 2020 through December 31, 2021 (84 FR 40699). We note that we correctly stated the dates of the first data collection period throughout the remainder of the proposed rule and confirm again here that the correct dates of the first data collection period are January 1, 2020 through December 31, 2020.

Comment: All commenters supported our proposal to allow ground ambulance organizations to report based on either a calendar year or their organization's fiscal year. We received no comments on the data collection period, and no comments on the proposal to allow a ground ambulance organization 5 months to report the data collected during data collection period.

Response: We appreciate the commenters' support of these proposals.

Comment: One commenter noted that internal systems of ground ambulance providers and suppliers will have to be changed during 2020 and that parameters will need to be edited in order to obtain quality data in a reasonable time.

Response: While we understand that system changes may be necessary for some ground ambulance organizations who are sampled in the first data collection period, we believe that most ground ambulance organizations will be able to complete the data collection requirements within the specified timeframe.

After consideration of the comments, we are finalizing the data collection period as a continuous 12-month period of time, which is either the calendar year aligning with the data collection year, or the organization's 12-month fiscal year that begins during the data collection year when an organization uses fiscal year for accounting purposes and elects to collect and report data over this period rather than the calendar year. We are also finalizing our proposal to allow a ground ambulance organization 5 months to report the data collected during data collection period. We are also finalizing our proposals to codify the data collection and reporting requirements for selected ground ambulance organizations at § 414.626(b).

7. Payment Reduction for Failure To Report

a. General Information and Applicable Period

Section 1834(l)(17)(D)(i) of the Act requires that beginning January 1, 2022, subject to clause (ii), the Secretary reduce the payments made to a ground ambulance organization under section 1834(l)(17) of the Act for the applicable period by 10 percent if the ground ambulance organization is required to submit data under the data collection system with respect to a data collection period and does not sufficiently submit such data. Section 1834(l)(17)(D)(ii) of the Act defines the applicable period as a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier failed to sufficiently submit information under the data collection system.

As previously discussed, we proposed to define the data collection and data reporting periods based on the ground ambulance organization's annual accounting period (either calendar year

or fiscal year). The timeline for the determination of the 10 percent reduction to payments would depend on: (1) The 12-month data collection period based on the organization's accounting period; (2) the end of the data reporting period that corresponds with the selected data collection period; and (3) the time it would take CMS to review the data to determine whether it had been sufficiently submitted. We proposed that we would make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than the date that is 3 months following the date that the ambulance organization's data reporting period ends. This timeframe will allow CMS to assess whether the required data was sufficiently submitted.

For example, if a ground ambulance organization is selected in the first sampling year and it reports to CMS that its annual accounting period is an October 1 through September 30th fiscal year, then its data collection period would be October 1, 2020 through September 30, 2021, and the data reporting period that would apply to the ground ambulance organization would be from October 1, 2021—February 28 (or 29, if a leap year), 2022. We would make a determination regarding the sufficiency of that ground ambulance organization's reporting no later than June 1, 2022. With this timeframe, we would propose to apply the 10 percent reduction in payments, if applicable, for ambulance services provided by that ground ambulance organization between January 1, 2023 and December 31, 2023, because under section 1834(l)(17)(D)(iii) of the Act, the applicable period must be one year in length. As another example, if a ground ambulance organization's annual accounting period is the calendar year, its data collection period would be January 1, 2020 through December 31, 2020, the data reporting period that would apply to the ground ambulance organization would be from January 1, 2021–May 31, 2021, and we would make a determination regarding the sufficiency of that ambulance organization's reporting no later than August 31, 2021. With this timeframe, we would propose to apply the 10 percent reduction in payments, if applicable, for ambulance services provided between January 1, 2022 and December 31, 2022. The payment reduction would always be applied to ground ambulance transports provided during the calendar year that begins following the date that we determine that the ground ambulance organization is subject to the payment reduction.

We proposed that if we find the data reported is not sufficient, we would notify the ground ambulance organization that it will be subject to the 10 percent payment reduction for ambulance services provided during the next calendar year. We would interpret ''sufficient'' to mean that the data reported by the ground ambulance organization is accurate and includes all required data requested on the data collection instrument.

We proposed to apply the 10 percent payment reduction for the appropriate calendar year as described above to ambulance fee schedule payments as described in § 414.610. The payment reduction will apply to claims for dates of service during the applicable calendar year and will be applied to the final ambulance fee schedule payment, after all other adjustments have been applied under § 414.610(c). We proposed to codify the payment reduction by adding a new paragraph (c)(9) in § 414.610.

b. Hardship Exemption

Section 1834(l)(17)(A)(D)(iii) of the Act authorizes the Secretary to exempt a ground ambulance provider or supplier from the 10 percent payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the ground ambulance provider or supplier to submit such information in a timely manner for the specified period.

We recognize that there may be some ground ambulance organizations that have limited resources that affect their ability to report the required information, and that for these ground ambulance organizations, a 10 percent payment reduction in Medicare payments could result in significant financial hardship.

An example of this situation could be a ground ambulance organization that is located in a super rural area with such limited resources that it cannot report the required information without significantly increasing the possibility that it would need to file for bankruptcy.

Another example could be a ground ambulance organization that is located in an area that had recently experienced a natural disaster such as widespread flooding that caused the closure of a local emergency room or other facilities. Due to the increased demand for services and rerouting of patients, this ground ambulance organization might be unable to collect and report information in a timely manner.

We proposed that ground ambulance organizations that have experienced these or other similar situations could request a hardship exemption, and we would consider granting an exemption if the ground ambulance organization could demonstrate that the significant hardship interfered with its ability to submit the required data under the data collection system.

To request a hardship exemption, we proposed that a ground ambulance organization submit to CMS a completed request form, which can be found on the Ambulance Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*), and that the following information be included:

- Ambulance Provider or Supplier Name;
- NPI Number;
- Ambulance Provider or Supplier Location Address;
- CEO and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable);
- Reason for requesting a hardship exemption;
- Evidence of the impact of the hardship exemption (such as photographs, newspaper, other media articles, financial data, bankruptcy filing, etc.); and
- Date when the ground ambulance organization would be able to begin submitting information under the data collection system.

We proposed that the completed hardship exemption request form be signed and dated by the Chief Executive Officer (CEO) or designee of the ambulance company, and be submitted as soon as possible, and not later than 90 calendar days after the date that the ground ambulance organization was notified that it will be subject to the 10 percent payment reduction as a result of not sufficiently submitting information under the data collection system. We proposed that the request form be submitted to the Ambulance ODF mailbox at *AMBULANCEODF@cms.hhs.gov.* Following receipt of the request form, we proposed to provide: (1) A written acknowledgement that the request has been received; and (2) a written response to the CEO and any designated personnel using the contact information provided in the request within 30 days of the date that we received the request. We also proposed to codify the hardship exemption requirement at § 414.626(d).

c. Informal Review

Section 1834(l)(17)(D)(iv) of the Act requires the Secretary to establish a process under which a sampled ground organization may seek an informal review of a determination that it is subject to the 10 percent reduction. To request an informal review, we proposed that a ground ambulance organization must submit the following information:

- Ground Ambulance Organization Name;
- NPI Number;
- CEO and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable);
- Ground ambulance organization's selected data collection period and data reporting period; and
- A statement of the reasons why the ground ambulance organization does not agree with CMS' determination and any supporting documentation.

We proposed that the informal review request must be signed by the CEO/designee of the ground ambulance organization and be submitted within 90 calendar days of the date that the ground ambulance organization received notice regarding the 10 percent reduction in payments. We proposed 90 calendar days to submit an informal review request to allow time for the ground ambulance organization to gather the information needed to support the request for informal review. We proposed that the request be submitted to the Ambulance ODF mailbox at *AMBULANCEODF@cms.hhs.gov.* Following receipt of the request for informal review, we will provide: (1) A written acknowledgement using the contact information provided in the request, to the CEO and any additional designated personnel, notifying them that the ambulance provider or supplier's request has been received; and (2) a written response to the CEO and any designated personnel using the contact information provided in the request within 30 days. We solicited comments on our informal review process. We also proposed to codify the informal review process in § 414.626(e).

We invited comments regarding all the proposals on the payment reduction for failure to report, including the applicable period, hardship exemption, and informal review.

We received comments on the proposals for the hardship exemption and informal review, and no comments on the applicable period. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposals regarding the hardship exemption and informal review. One commenter noted that the majority of patients in rural/super rural areas are Medicare beneficiaries and that in these areas, the ground ambulance organization may have a small call volume. The commenter stated that the ground ambulance organization may not understand how to complete the survey, and the financial impact of the 10 percent reduction would impact the ground ambulance organization's ability to stay in business. One commenter requested clarification on the length and timing of the 10 percent reduction for failure to report.

Response: We appreciate the support of the commenters. We will provide education and outreach to ground ambulance organizations that are selected to participate in the ground ambulance data collection system and will work directly with the affected organizations to the extent possible. As previously noted, the payment reduction would always be applied to ground ambulance transports provided during the calendar year for a one year period that begins following the date that we determine that the ground ambulance organization is subject to the payment reduction.

Comment: Some commenters supported the proposed process for applying for a hardship exemption. One commenter stated that the form and timeline seem appropriate and sufficient to allow ambulance organizations to seek the exemption. One commenter asked that CMS provide automatic hardship exemptions when a deadline falls during the period of natural disaster, such as a hurricane.

Response: We appreciate the support of the commenters on the proposed process for hardship exemption. While we understand that a natural disaster may affect the ground ambulance organization's ability to collect or submit the required data, we are unable to provide an automatic hardship exemption. Unless the ground ambulance organization applies for the exemption, we would have no way of knowing which ground ambulance organizations are affected or to what extent the disaster has affected them. All ground ambulance organizations that are selected to participate in the data collection system have up to 5 months to report the data collected during the data collection period, and we encourage them not to wait for the deadline to report. We understand it may be difficult to meet a deadline during a natural disaster and we will work with the affected ground ambulance organization to the extent possible.

Comment: A commenter requested clarification regarding when the hardship exemption form will be available and when the organization can apply for the exemption. Another commenter requested information on how the hardship exemption request will be evaluated.

Response: The hardship exemption request form will be available on our website when this final rule is published. A ground ambulance organization that has been selected to report cost, revenue, utilization, and other information under the ground ambulance data collection system may apply for a hardship exemption during their data collection period if they have experienced a hardship that prevents them from submitting the required information. Again, we remind organizations that they have 5 months to report their data and should try to submit it as soon as possible to avoid this type of situation. All hardship exemption requests will be evaluated based on the information submitted that clearly shows that they are unable to submit the required data due to a significant hardship, such as a natural disaster, bankruptcy, or other similar situation.

Comment: Some commenters supported the informal review process that we proposed to adopt and asked that we permit ground ambulance organizations to address any problems with their submitted data originally during a defined time period and without having to incur a payment reduction. The commenters stated that this correction would be prudent because of the lack of testing of the data collection instrument.

Response: We will work with the affected organization to the extent possible to correct any mistakes or omissions in the data they submitted in order to avoid incurring a payment reduction.

After consideration of the comments, we are finalizing all of our proposals regarding on the payment reduction for failure to report, including the applicable period, hardship exemption, and informal review. We are also finalizing our proposal to codify the payment reduction by adding a new paragraph (c)(9) in § 414.610, our proposal to codify the hardship exemption requirement at § 414.626(d) and our proposal to codify the informal review process at § 414.626(e). In the proposed rule, we inadvertently stated that the informal review process would

be codified at § 414.610(e) (84 FR 40701).

Hardship exemption and informal review requests should be submitted to the Ambulance ODF mailbox at: *AMBULANCEODF@cms.hhs.gov.* Questions on the ground ambulance data collection system should be sent to *AmbulanceDataCollection@cms.hhs.gov.*

8. Public Availability

Section 1834(l)(17)(G) of the Act requires that the results of the data collection be posted on the CMS website, as determined appropriate by the Secretary. We proposed to post on our website a report that includes summary statistics, respondent characteristics, and other relevant results in the aggregate so that individual ground ambulance organizations are not identifiable.

We also proposed that the data above will be made available to the public through posting on our website at least every 2 years. The 2-year timeframe would allow CMS time to analyze the data that is being reported, factoring in the various accounting periods of the first group of sampled ground ambulance organizations (which have early accounting periods in the CY 2020 data collection year).

We proposed to post summary results by the last quarter of 2022, because we believe we may have most or all of the data requested by then. We invited comments on our proposals regarding the type of information that should be posted from the data collected and the timeline in which the results of the data collection should be posted on our website.

We invited comments regarding our proposals for public availability of the data.

We received comments on our proposals regarding the type of information that should be posted from the data collected, the timeline in which the results of the data collection should be posted on our website, and the public availability of the data.

The following is a summary of the comments we received and our responses.

Comment: One commenter stated that the report should be more detailed than the proposed summary statistics, respondent characteristics, and other relevant results in the aggregate. One commenter recommended that the data collected through the data collection system be made publicly available in various formats such as Public Use Files (PUF) accessible through the web, or other formats that will facilitate the use of the data for other purposes.

One commenter stated it is important that stakeholders have access to the data collection in a manner that is similar to the publicly available data obtained through traditional Medicare cost reporting. Some commenters encouraged CMS to incorporate the ambulance cost data into the standard Healthcare Cost Report Information System (HCRIS) as an additional subsystem to the ground ambulance data collection system.

One commenter recommended that CMS follow the standard HCRIS file format and schedule for releasing ambulance cost data, including releasing two types of data files. This commenter recommended that the ambulance cost report PUF contain a subset of the data variables reported by ambulance suppliers and providers and may enable users to calculate provider margins and assess ambulance transport volume. The commenter requested data be available in multiple formats and also stated that CMS should follow the standard file formats as it releases these files to reduce the burden on researchers. The commenter also recommended that all ambulance cost report variables be defined with Medicare's Provider Reimbursement Manual. Lastly, the commenter stated that the individual ground ambulance organizations should not be identifiable in the results of the data collection on our website.

Response: We thank the commenters for their recommendations regarding the posting of the results of the data collection on the CMS website. We are exploring several mechanisms for posting of the report to our website. As such, we will consider the use of HCRIS and other PUFs to make the data publicly available. We intend to post as much data as possible, including summary statistics describing the data reported by subgroups of respondents, while protecting the confidentiality of the respondents.

Comment: One commenter stated that the information should be published more frequently than once every 2 years.

Response: We believe that the 2-year timeframe would allow us time to analyze the reported data, factoring in the various accounting periods. We will make the data available more frequently if possible.

Comment: Several commenters supported our proposal to make the data collected through the data collection system publicly available. One commenter stated that the data collected through the data collection system will be exceptionally valuable for agencies, payors, policy makers and other stakeholders and they recommend that the data be publicly available. One commenter stated that it is important that stakeholders have access to the data to be able to evaluate the adequacy of the payment system, not just MedPAC or other policymakers.

One commenter preferred that these data be shared publicly to provide more transparency in ambulance service rates. One commenter stated that given that this is the early stages of the development of the ambulance data collection system and the lack of testing, CMS might consider restricting access to the data in the first few years to only key stakeholders. This commenter stated that key stakeholders may be able to assist the agency with validating the initial data submitted by ambulance suppliers and providers.

Response: We appreciate the support of the commenters on our public availability proposals. We agree that making the data publically available is the most transparent approach and we anticipate that the data we make publicly available will be meaningful to all interested persons or organizations.

We did not receive any comments regarding our proposal to post summary results by the last quarter of 2022. After consideration of the comments, we are finalizing our proposals for public availability of the data including to post on our website a report that includes summary statistics, respondent characteristics, and other relevant results in the aggregate so that individual ground ambulance organizations are not identifiable. The data above will be made available to the public through posting on our website at least every 2 years and we will post summary results by the last quarter of 2022.

9. Limitations on Review

Section 1834(l)(17)(J) of the Act provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the data collection system or identification of respondents. We proposed to codify the limitations on review at § 414.626(g). We did not receive any comments on this proposal and are finalizing it as proposed.

C. Expanded Access to Medicare Intensive Cardiac Rehabilitation (ICR)

Section 51004 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, enacted February 9, 2018) amended section 1861(eee)(4)(B) of the Act directing CMS to add covered conditions for intensive cardiac rehabilitation (ICR). This final rule expands coverage through revisions to § 410.49(b)(1).

1. Background

Cardiac rehabilitation (CR) was developed in the 1950s from the concept of early mobilization after acute myocardial infarction (heart attack).[99] The standard of care prior to the widespread adoption of CR was bed-rest and inactivity after acute myocardial infarction.[100] In the 1970s, cardiac rehabilitation developed into highly structured, physician supervised, electrocardiographically-monitored exercise programs. However, the programs consisted almost solely of exercise alone.[101] Forman (2000) stated that ''over subsequent years the objectives of cardiac rehabilitation broadened beyond exercise into a composite of cardiac risk modification. Lipid, blood pressure, and stress reduction, smoking cessation, diet change, and weight loss were coupled to goals of exercise training.''

ICR, also commonly referred to as a ''lifestyle modification'' program, typically involves the same elements as traditional CR programs, but are furnished in highly structured environments in which sessions of the various components may be combined for longer periods of CR and also may be more rigorous.

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted July 15, 2008) amended Title XVIII to add new section 1861(eee) of the Act to provide coverage of CR and ICR under Medicare Part B. The statute specified certain conditions for these services and an effective date of January 1, 2010, for coverage of these services. Conditions of coverage for CR and ICR consistent with the statutory provisions of section 144(a) of the MIPPA were codified in § 410.49 through the CY 2010 PFS final rule with comment period (74 FR 61872–61879 and 62004–62005). These programs were designed to improve the health care of Medicare beneficiaries with cardiovascular disease.

Under § 410.49(b), Medicare Part B covers CR and ICR program services for beneficiaries who have experienced one or more of the following: (1) An acute myocardial infarction within the preceding 12 months; (2) a coronary artery bypass surgery; (3) current stable angina pectoris; (4) heart valve repair or replacement; (5) percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or (6) a heart or heart-lung transplant. For CR only, other cardiac conditions may be added as specified through a national coverage determination (NCD). Effective February 18, 2014, we expanded coverage of CR in NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (Pub. 100–03 20.10.1), to beneficiaries with stable, chronic heart failure, defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. Stable patients are defined as patients who have not had recent (≤ 6 weeks) or planned (≤ 6 months) major cardiovascular hospitalizations or procedures.

2. Statutory Authority

Section 51004 of the BBA of 2018, entitled ''Expanded Access to Medicare Intensive Cardiac Rehabilitation Programs,'' amended section 1861(eee)(4)(B) of the Act. The amendment directs us to expand the list of covered conditions for ICR beyond the 6 conditions specified in section 144(a) of the MIPPA and codified in § 410.49(b)(1).

3. Discussion of Statutory Requirements

Section 1861(eee)(4)(B) of the Act requires that, in addition to the 6 conditions specified in section 144(a) of the MIPPA, ICR be covered for beneficiaries with (1) stable, chronic heart failure (defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks); or (2) any additional condition for which the Secretary has determined that a cardiac rehabilitation program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.

The statute explicitly states *cardiac* rehabilitation; therefore, this final rule is specific to CR and ICR for cardiac conditions. As such, this final rule cannot exceed the limits of the statute to apply CR and ICR other conditions (for example, cancer, metabolic syndrome, diabetes, peripheral artery disease, etc.).

4. Proposals for Implementation

We proposed to amend § 410.49(b) to expand the covered conditions for ICR. We proposed to amend § 410.49(b)(vii) to add coverage of ICR for patients with stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. We also proposed to specify in § 410.49(b)(vii) that coverage for CR was effective February 18, 2014 as per the NCD for Cardiac Rehabilitation for Chronic Heart Failure (Pub. 100–03 20.10.1) which was finalized on February 18, 2014 as discussed above, and that coverage for ICR was effective on enactment of the BBA of 2018 (February 9, 2018).

We also proposed to add new § 410.49(b)(viii) to include coverage of ICR, in addition to CR, for other cardiac conditions as specified through an NCD. Under the existing § 410.49(b)(vii), coverage for CR may be established for other cardiac conditions through an NCD, and this final rule will extend this criterion to ICR, as well unless coverage for ICR is not supported by clinical evidence. As such, NCDs modifying the covered conditions would apply to both CR and ICR so long as clinical evidence supports coverage for CR and coverage for ICR.

It is important to note that conditions that may be considered for expanded coverage are limited to cardiac conditions and may not include other conditions (for example, cancer, metabolic syndrome, diabetes, peripheral artery disease, etc.).

5. Comments

We received public comments on this proposal and some were outside the scope.

Comment: Several commenters supported this proposal. In particular, they supported the alignment of the CR and ICR covered conditions and utilization of the NCD process to expand ICR covered conditions in the future. Many of these commenters suggested that our proposal was consistent with the underlying statute.

Response: We appreciate the commenter's support to codify in regulations the provisions of section 51004 of the BBA.

Comment: Several commenters submitted comments on this proposal that were outside of the scope of the proposed rule. For example, these comments touched upon authorizing other health care providers to order and supervise CR; extending coverage of CR

[99] Pashkow, FJ. Issues in Contemporary Cardiac Rehabilitation: A Historical Perspective. JACC 1993 Mar 1;21(3):822–34.

[100] Forman DE. Cardiac rehabilitation and secondary prevention programs for elderly cardiac patients. Clin Geriatr Med. 2000 Aug;16(3):619–29.

[101] Ades PA. A controlled trial of cardiac rehabilitation in the home setting using electrocardiographic and voice transtelephonic monitoring. Am Heart J. 2000 Mar;139(3):543–8.

to non-cardiac related conditions; and altering existing NCDs.

Response: We appreciate the commenters' interest in the CR and ICR topics. However, because these comments were outside of the scope of the proposed rule, we are not responding to them in this final rule.

In summary, we are finalizing modifications to § 410.49(b) to implement the coverage changes specific to ICR. This includes expanding coverage of ICR to beneficiaries with chronic heart failure as discussed above and providing for modifications to covered cardiac conditions for ICR, in addition to CR, as specified through an NCD.

D. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

1. Background

Sections 1903(a)(3)(F) and (t) of the Act provide the statutory basis for the incentive payments made to Medicaid EPs and eligible hospitals for the adoption, implementation, upgrade, and meaningful use of Certified EHR Technology (CEHRT). We have implemented these statutory provisions in prior rulemakings to establish the Medicaid Promoting Interoperability Program.

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act, and the definition of ''meaningful EHR user'' in regulations at 42 CFR 495.4, one of the requirements of being a meaningful EHR user is to successfully report the clinical quality measures selected by CMS to CMS or a state, as applicable, in the form and manner specified by CMS or the state, as applicable. Section 1848(o)(2)(B)(iii) of the Act requires that in selecting electronic clinical quality measures (eCQMs) for EPs to report under the Promoting Interoperability Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. We have taken steps to align various quality reporting and payment programs that include the submission of eCQMs.

In the CY 2019 PFS final rule (83 FR 59452, 59703 through 59704), we established for 2019 that Medicaid EPs are required to report on any six eCQMs that are relevant to the EP's scope of practice, regardless of whether they report via attestation or electronically. We also adopted the Merit-based Incentive Payment System (MIPS) requirement that EPs report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure). We explained that if no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, the EP may report on any six eCQMs that are relevant.

2. eCQM Reporting Requirements for EPs Under the Medicaid Promoting Interoperability Program for 2020

We annually review and revise the list of eCQMs for each MIPS performance year to reflect updated clinical standards and guidelines. In section III.I.3.h.(2)(b)(i) of this final rule, we amend the list of available eCQMs for the CY 2020 performance period. To keep eCQM specifications current and minimize complexity, we proposed to align the eCQMs available for Medicaid EPs in 2020 with those available for MIPS eligible clinicians for the CY 2020 performance period. Specifically, we proposed that the eCQMs available for Medicaid EPs in 2020 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2020 performance period.

In previous years, CMS proposals to align the list of eCQMs for MIPS and the Medicaid Promoting Interoperability Program for EPs received positive comments that indicated that alignment between these two programs would reduce health care provider reporting burden (83 FR 59702). These comments thus suggest that aligning the eCQM lists might encourage EP participation in the Medicaid Promoting Interoperability Program by giving Medicaid EPs that are also MIPS eligible clinicians the ability to report the same eCQMs as they report for MIPS. Not aligning the eCQM lists could lead to increased burden, because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program if they opt to report on newly added eCQMs for MIPS. In addition, we believe that aligning the eCQMs available in each program would help to ensure the most uniform application of up-to-date clinical standards and guidelines possible.

We anticipated that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, particularly in light of our belief that many EPs would report eCQMs to meet the quality performance category of MIPS, and therefore, should be prepared to report on the available eCQMs for 2020. We expected that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2020 to maintain current eCQM lists and specifications.

For 2020, we proposed to again require (as we did for 2019) that Medicaid EPs report on any six eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically. This policy of allowing Medicaid EPs to report on any six measures relevant to their scope of practice would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established at § 414.1335(a)(1). MIPS eligible clinicians who elect to submit eCQMs must generally submit data on at least six quality measures, including at least one outcome measure (or, if an applicable outcome measure is not available, one other high priority measure). We refer readers to § 414.1335(a) for the data submission criteria that apply to individual MIPS eligible clinicians and groups that elect to submit data with other collection types.

In addition, as we did for 2019, we proposed that for 2020, EPs in the Medicaid Promoting Interoperability Program would be required to report on at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure). This policy would improve alignment with the requirements for the MIPS quality performance category for eligible clinicians using the eCQM collection type. We also proposed that if no outcome or high priority measures are relevant to a Medicaid EP's scope of practice, the clinician may report on any six eCQMs that are relevant, as was the policy in 2019.

In the CY 2019 PFS final rule (83 FR 59702 and 59704), we established the following three methods to identify which of the available measures are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program in 2019. We proposed to use the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2020:

- The same set of measures that are identified as high priority measures for reporting on the quality performance category for eligible clinicians participating in MIPS.
- All e-specified measures from the previous year's core set of quality measures for Medicaid and the Children's Health Insurance Program (CHIP) (Child Core Set) or the core set of health care quality measures for

adults enrolled in Medicaid (Adult Core Set) (hereinafter together referred to as ''Core Sets'') that are also included on the MIPS list of eCQMs.

Sections 1139A and 1139B of the Act require the Secretary to identify and publish core sets of health care quality measures for child Medicaid and CHIP beneficiaries and adult Medicaid beneficiaries. These measure sets are required by statute to be updated annually and are voluntarily reported by states to CMS. These Core Sets are composed of measures that specifically focus on populations served by the Medicaid and CHIP programs and are of particular importance to their care. The MIPS eCQM list includes several, but not all, of the measures in the Core Sets. Because the Core Sets are released at the beginning of each year, it is not possible to update the list of high-priority eCQMs with those added to the current year's Core Sets.

The eCQMs that would be available for Medicaid EPs to report in 2020, that are both part of the Core Sets and on the MIPS list of eCQMs, and that we proposed would be considered high priority measures were: CMS2, ''Preventive Care and Screening: Screening for Depression and Follow-Up Plan''; CMS122, ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)''; CMS125, ''Breast Cancer Screening''; CMS128, ''Anti-depressant Medication Management''; CMS136, ''Follow-Up Care for Children Prescribed ADHD Medication (ADD)''; CMS137, ''Initiation and Engagement of Alcohol and Other Drug Dependence Treatment''; CMS153, ''Chlamydia Screening for Women''; CMS155, ''Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents''; and CMS165, ''Controlling High Blood Pressure.''

- Through an amendment to § 495.332(f), we gave each state the flexibility to identify which of the eCQMs available for reporting in the Medicaid Promoting Interoperability Program are high priority measures for Medicaid EPs in that state, subject to CMS' review and approval, through the State Medicaid HIT Plan (SMHP). States are thus able to identify high priority measures that align with their state health goals or other programs within the state.

All eCQMs identified via any of these three methods are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program for 2019. As noted above, we proposed to use the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2020. We invited comments as to whether any of these methods should be altered or removed, or whether any additional methods should be considered for 2021.

We received public comments on aligning the available eCQMs for the Medicaid Promoting Interoperability Program with those available under the eCQM collection type for the MIPS CY 2020 performance period, the requirement that Medicaid EPs must submit any six eCQMs relevant to an EP's scope of practice, including one outcome measure (or if an outcome measure is not available or relevant, one high priority measure), and the three methods we proposed for identifying high priority measures. The following is a summary of the comments we received and our responses.

Comment: All comments we received on these topics were supportive of our proposals.

Response: We thank commenters for their support.

After considering public comments, we are finalizing these policies as proposed. The eCQMs available for Medicaid EPs in 2020 will consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2020 performance period. In 2020, Medicaid EPs will be required to report on any six eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically. For a reporting period in CY 2020, Medicaid EPs will be required to report on at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure). If no outcome or high priority measures are relevant to a Medicaid EP's scope of practice, the clinician may report on any six eCQMs that are relevant. eCQMs identified via any of the three methods discussed above will be high priority measures for EPs participating in the Medicaid Promoting Interoperability Program in 2020.

We also proposed that the 2020 eCQM reporting period for Medicaid EPs who have demonstrated meaningful use in a prior year would be a minimum of any continuous 274-day period within CY 2020. This 274-day eCQM reporting period corresponds to the 9-month period from January 1, 2020 to September 30, 2020. We explained that under our proposal, Medicaid EPs would not be required to use that exact reporting period, but would be able to use any continuous 274-day period within CY 2020. We also explained that Medicaid EPs could also use a longer eCQM reporting period in CY 2020, up to the full calendar year. We noted that states would be required to allow sufficient time for EPs to attest for program year 2020 beyond January 1, 2021 so that EPs may, should they choose to do so, select EHR and eCQM reporting periods that take place at any time within the 2020 calendar year through December 31, 2020.

We proposed this eCQM reporting period for 2020 to improve state flexibility in the penultimate year of the Medicaid Promoting Interoperability Program, and to facilitate an orderly end of the program in 2021. In the CY 2019 PFS final rule, we established that the eCQM reporting period for Medicaid EPs in 2021 will be a minimum of any continuous 90-day period within CY 2021, and also established that the end date for this period must fall before October 31, 2021, to help ensure that states can issue all Medicaid Promoting Interoperability payments to EPs by the December 31, 2021 statutory deadline (83 FR 59704 through 59706). When proposing that policy, we received comments that asked us to consider an eCQM reporting period shorter than a full year in 2020. Commenters on the CY 2019 PFS proposals stated that a full-year reporting period may create significant backlogs of 2020 and 2021 attestations in 2021 that may create difficulty for states to issue payments by the statutory deadline (83 FR 59705). We continue to believe that a full year reporting period creates more useful data for quality measurement and improvement because it would give states a broader picture of the care rendered by a health care provider and patient outcomes. However, we agree that a full-year eCQM reporting period in 2020 would unnecessarily burden states as they will need to issue incentive payments and implement systems changes for 2021 in a timely manner.

We explained that this proposal would allow states to accept attestations for program year 2020 as early as October 1, 2020 from Medicaid EPs who choose to use an eCQM reporting period early in the year, and thus could give states additional time to prepare for 2021 and the end of the Medicaid Promoting Interoperability Program. We explained that even though states would also still have to allow EPs to submit attestations for 2020 in 2021, we believe that allowing some EPs to attest sooner could accelerate states' pre-payment verification and payment process. We explained that we considered whether to propose a Medicaid EP eCQM reporting period for 2020 from January 1, 2020 through September 30, 2020, with no flexibility for EPs to select an

alternative 274-day eCQM reporting period. We also considered whether to propose a date prior to December 31, 2020 by which all Medicaid EP EHR and eCQM reporting periods for 2020 must end. While either of these alternatives might have further helped to ensure that all states would have additional time to prepare for 2021, we decided not to propose either of them because we wanted to preserve as much flexibility as possible for Medicaid EPs. However, we solicited comment, especially from states and Medicaid EPs, about whether either of these alternatives might be preferable to our proposal.

We noted that states submit their attestation deadlines to CMS each year as part of their SMHPs. We did not believe that this proposal would create any additional burden on EPs or health IT vendors, as CEHRT should be able to report eCQM data with respect to any period of time.

We proposed that, in 2020, the eCQM reporting period for Medicaid EPs demonstrating meaningful use for the first time, which was established in the final rule entitled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017'' (80 FR 62762, 62892) (hereinafter known as the ''Stage 3 final rule''), would remain any continuous 90-day period within the calendar year, as in previous years.

The following is a summary of the comments we received about the proposed eCQM reporting period for CY 2020, and our responses.

Comment: All commenters supported the principle of our proposal to shorten the eCQM reporting period for CY 2020. Some commenters noted that eCQMs are developed for a full-year reporting period, and that any reporting period shorter than a year (regardless of length) will inherently introduce data quality issues, but agreed that shortening the reporting period in order to facilitate 2020 and 2021 payments was an overriding concern. However, most commenters opposed a 274-day reporting period for CY 2020, and instead urged us to establish a 90-day eCQM reporting period for CY 2020. No commenters supported a fixed reporting period (for example, from January 1, 2020 to September 30, 2020); most commenters objected to a fixed reporting period on the grounds that allowing EPs to select their own reporting period would increase their flexibility to meet the program requirements.

The comments suggesting that we instead establish a 90-day eCQM reporting period for 2020 came from a variety of stakeholders, including provider organizations, health IT vendors, and state Medicaid agencies. These commenters presented several rationales in support of a 90-day eCQM reporting period. First, many of these commenters noted that we have never used an EHR or eCQM reporting period other than a full year or 90 days for EPs, so establishing a one-time 274-day eCQM reporting period for 2020 would be confusing to EPs. A couple of commenters suggested that a 90-day reporting period was much simpler, but that a reporting period based on the calendar quarter or even a full year would be less confusing for EPs than a 274-day reporting period. Second, one commenter suggested that a 90-day eCQM reporting period might actually produce data that could be more useful for longitudinal analytics than a 274-day reporting period, because a 90-day reporting period would align with the already-established 90-day eCQM reporting period for 2021. Third, some of these commenters asserted that a 90-day eCQM reporting period would reduce the administrative and reporting burden for EPs because it would be aligned with the eCQM reporting period for MIPS eligible clinicians. These commenters thought that there would be a 90-day reporting period for eligible clinicians in MIPS who choose the eCQM collection type.

We also received comments discussing whether CEHRT should be able to report eCQMs for any length of time. One health IT vendor agreed that CEHRT should be able to report eCQMs for any length of time, while another commenter stated that its systems would require additional coding to produce eCQM data for a 274-day reporting period.

Response: After considering these comments, we agree with the commenters that finalizing a 274-day eCQM reporting period only for CY 2020 may cause confusion for Medicaid EPs. The Medicaid Promoting Interoperability Program has always used reporting periods of a full year or 90 days for EPs. We believe that finalizing a 90-day eCQM reporting period for 2020, as recommended by commenters, instead of the 274-day eCQM reporting period we proposed, is more likely to reduce burden on EPs, health IT vendors, states, and other stakeholders, as compared to a full-year period or the 274-day eCQM reporting period we proposed.

A 90-day eCQM reporting period in 2020 will reduce burden on Medicaid EPs because it will provide EPs with additional time during which they can attest (depending on when their state accepts attestations for 2020). It could reduce burden on states by enabling states to take EP attestations earlier during 2020, which could help states perform the necessary prepayment process and issue incentive payments for 2020 over a longer period of time while they prepare for the final year of the program in 2021. While certain health IT vendors submitted comments that generally confirmed our understanding that CEHRT should be able to run reports for any period of time, as outlined in the proposed rule, one commenter noted that there may be some CEHRT products that would need additional coding for a new reporting period length versus the previously-used 90-day eCQM reporting period. Thus, finalizing a 90-day eCQM reporting period could also reduce burden on at least some health IT vendors. Furthermore, this policy would allow EPs to use the same 90-day period for their Medicaid Promoting Interoperability Program EHR reporting period and eCQM reporting period.

As noted above, we continue to believe that a full year eCQM reporting period would lead to better data quality than a shorter period. We also agree that any eCQM reporting period shorter than a full year is inherently going to introduce data quality issues, whether it is a 274-day or 90-day period. However, we acknowledge that a 90-day eCQM reporting period in 2020 would match the already-established 90-day eCQM reporting period for 2021, and thus might provide better data for comparison than a 274-day period. Ultimately, we concluded that the risk of any possible data quality degradation due to a shorter reporting period might be somewhat mitigated by using a period that can be compared across program years 2020 and 2021. We also concluded that, generally, the potential data quality issues associated with a shorter eCQM reporting period are outweighed by the benefits to all stakeholders of a shorter period for 2020.

While we generally agreed with the commenters recommending we establish a 90-day eCQM reporting period, the comments recommending that we do so specifically in order to align with MIPS reporting were based on a mistaken assumption. We are establishing a full-year reporting period for the MIPS quality performance category, in section III.K.3.c.(1) of this final rule, as we did for 2018 and 2019. While a 90-day eCQM reporting period in 2020 for the Medicaid Promoting Interoperability Program would not be aligned with this MIPS reporting period, we believe that, for the reasons

discussed above and in the proposed rule preamble, a period shorter than a full year would provide helpful flexibility to Medicaid EPs and states, and that these benefits outweigh any potential burdens created by the lack of alignment. No commenters suggested to us that aligning the eCQM reporting period for 2020 with the full year reporting period for MIPS eligible clinicians who use the eCQM collection type outweighed the benefits of the shorter reporting period that we proposed.

After considering the comments, we are finalizing a continuous 90-day eCQM reporting period for all Medicaid EPs in 2020. EPs may select any continuous 90-day period within the calendar year. The reporting period is a minimum, and we encourage EPs to report on a longer period if they are able to do so.

Under this policy, EPs may be able to attest to meaningful use as early as April 1, 2020. We encourage states to begin taking attestations as early as possible in 2020, as that would allow states as much time as possible to process and make 2020 payments before they have to prepare for the 2021 program year. Just as we proposed in connection with the 274-day eCQM reporting period, we expect states to provide EPs the opportunity to use any 90-day period in 2020 under the finalized policy, up to and including a period that ends December 31, 2020. Therefore, states must allow sufficient time for EPs to attest into CY 2021. As noted in the proposed rule and above, states submit their attestation deadlines to CMS for approval each year as part of their SMHPs.

3. Objective 1: Protect Patient Health Information in 2021

In the Stage 3 final rule (80 FR 62762, 62832), we established Meaningful Use Objective 1 as ''Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.'' As specified at § 495.24(d)(1)(i)(B), to meet that objective, EPs must meet the associated measure to conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

In the Stage 3 final rule, we explained that this measure must be completed in the same calendar year as the EHR reporting period. This may occur before, during, or after the EHR reporting period, though if it occurs after the EHR reporting period it must occur before the provider attests to meaningful use of CEHRT or before the end of the calendar year, whichever comes first (80 FR 62831). In practice, this means that EPs do not attest to meaningful use of CEHRT before completing this measure.

As discussed above, states must issue all Medicaid Promoting Interoperability Program incentive payments by the statutory deadline of December 31, 2021. States can establish state-specific deadlines for Medicaid EPs to attest to the state regarding meaningful use of CEHRT in CY 2021. However, due to changes CMS made in prior rulemaking to the Medicaid Promoting Interoperability Program EHR and eCQM reporting periods for 2021, all states must set attestation deadlines on or before October 31, 2021. *See* 42 CFR 495.4 (definition of ''EHR reporting period'') and 495.332(f)(3) and (4), and 83 FR 59704 through 59705. Because all EPs are expected to attest to meaningful use of CEHRT before the end of CY 2021, Medicaid EPs would no longer have the option of completing the security risk analysis at the end of the calendar year, and would likely have to complete it well before December 2021. For example, in a state with an attestation deadline of October 1, 2021, a Medicaid EP would have to conduct the security risk analysis by September 30, 2021. Stakeholders have offered us feedback that most security risk analyses are conducted on a clinic or practice level, which may include EPs and non-EPs. As we noted in the Stage 3 final rule, ''[a]n organization may conduct one security risk analysis or review which is applicable to all EPs within the organization, provided it is within the same calendar year and prior to any EP attestation for that calendar year. However, each EP is individually responsible for their own attestation and for independently meeting the objective. Therefore, it is incumbent on each individual EP to ensure that any security risk analysis or review conducted for the group is relevant to and fully inclusive of any unique implementation or use of CEHRT relevant to their individual practice'' (80 FR 62794).

If an EP or practice typically conducts the security risk analysis at the end of each year, the CY 2021 timeline for attesting to meaningful use of CEHRT may create burden for all Medicaid EPs and for non-EP health care providers within the same organization as Medicaid EPs, and may not be optimal for protecting information security, because it could disrupt the intervals between security risk analyses. As we explained in the Stage 3 final rule, a security risk analysis is not a discrete item in time, but a comprehensive analysis covering the full period of time for which it is applicable; and the annual review of such an analysis is similarly comprehensive. In other words, the analysis and review, no matter when they are conducted, should *not* be just a ''point in time'' exercise, and instead should cover a span of the entire year, including a review planning for future system changes within the year or a review of prior system changes within the year (80 FR 62831). However, EPs that typically conduct the security risk analysis in December of each calendar year might conduct one security risk analysis in December 2020, and then have to conduct another one well before December 2021, if the analysis must be completed before the EP attests to meaningful use of CEHRT for CY 2021. We believe that security risk analyses are most effective for data security when conducted on a regular schedule. In addition, practice locations may have ongoing contracts or processes in place to perform a security risk analysis at the same time each year. We do not wish to create burden for EPs and non-EPs related to changing those processes to meet the CY 2021 Medicaid Promoting Interoperability Program attestation timelines.

Therefore, we proposed to allow Medicaid EPs to conduct a security risk analysis at any time during CY 2021, even if the EP conducts the analysis after the EP attests to meaningful use of CEHRT to the state. A Medicaid EP who has not completed a security risk analysis for CY 2021 by the time he or she attests to meaningful use of CEHRT for CY 2021 would be required to attest that he or she will complete the required analysis by December 31, 2021. Under this proposal, states could require Medicaid EPs to submit evidence that the security risk analysis has been completed as promised, even after the incentive payment has been issued. In addition, states could require EPs to attest that if a security risk analysis is not completed by December 31, 2021, they will voluntarily rescind their attestation to meaningful use of CEHRT and return the incentive payment. We explained that if this proposal is finalized, we would work with states to develop post-payment verification and audit processes that meet CMS due diligence requirements,

including those in §§ 495.318 and 495.368, and generally to ensure that incentive payments are made properly. We reminded states that as a condition of receiving enhanced federal financial participation, they are required to demonstrate to the satisfaction of HHS that they are conducting adequate oversight of the program, including routine tracking of meaningful use attestations (*See* § 495.318(b)). We also reminded states that they must submit a description of the methodology used to verify that EPs have meaningfully used CEHRT for CMS approval as part of their SMHP. (*See* § 495.332(c)). In the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program'' (75 FR 44313), CMS explained that states are expected to ''look behind'' provider attestations, and that this would require audits both pre- and post-payment (75 FR 44515). These requirements and expectations would not change under this proposal.

The following is a summary of the comments we received on our proposed changes, and our responses.

Comment: The majority of commenters stated their support for our proposal to allow Medicaid EPs to conduct a security risk analysis (SRA) at any time during CY 2021, even if the EP conducts the analysis after the EP attests to meaningful use of CEHRT to the state. These commenters stated that allowing EPs to complete the security risk analysis after their attestation will provide flexibility to EPs while allowing states sufficient time to process incentive payments in the final year of the program.

Response: It is our intention to allow for maximum flexibility for Medicaid EPs to attest before their state's 2021 deadline, while maintaining their annual SRA schedule.

Comment: A few commenters, including state Medicaid agencies, opposed our proposal to allow EPs to conduct their SRA after the EP attests to meaningful use of CEHRT to the state. These commenters expressed concern about program integrity risk, as well as the burden on state Medicaid agencies to ensure that these EPs are able to demonstrate that they met the program requirements. In addition, the commenters were concerned that the proposed policy might result in a greater number of recouped payments as a result of EPs not actually meeting the requirements.

Response: We believe safeguards are available to mitigate program integrity risk, such as requiring Medicaid EPs to submit evidence of their SRA once it is complete. Because the final incentive payments must be issued by December 31, 2021, we are limited in our ability to provide flexibility to Medicaid EPs given that all states must set attestation deadlines on or before October 31, 2021. Our policy is motivated by a desire to reduce overall burden on Medicaid EPs. We acknowledge there is some potential additional burden associated with increased monitoring by state Medicaid agencies and an increased risk of recoupments from what we believe would likely be a small minority of EPs. However, we believe this additional burden is clearly outweighed by the reduced burden on what we anticipate would be the vast majority of Medicaid EPs that are afforded flexibility to conduct the SRA at any point in the calendar year that aligns with their operational needs. Additionally, as noted above, states are already required to conduct adequate oversight of the Medicaid Promoting Interoperability Program, and we intend to work with states to develop post-payment verification and audit processes that meet CMS due diligence requirements, and generally to ensure that incentive payments are made properly. We have established at § 495.322(b) that 90 percent federal financial participation will be available for state administrative expenditures related to Medicaid Promoting Interoperability Program audits and appeals that are incurred on or before September 30, 2023.

After considering public comments, we are finalizing this policy as proposed, and will allow Medicaid EPs to conduct a security risk analysis at any time during CY 2021, even if the EP conducts the analysis after the EP attests to meaningful use of CEHRT to the state. A Medicaid EP who has not completed a security risk analysis for CY 2021 by the time he or she attests to meaningful use of CEHRT for CY 2021 will be required to attest that he or she will complete the required analysis by December 31, 2021.

4. Clarification

In the CY 2019 PFS final rule (83 FR 59702), in the list of high priority eCQMs that are available for Medicaid EPs to report in 2019 because they are both part of the Core Sets and on the MIPS list of eCQMs, we inadvertently listed ''Initiation and Engagement of Alcohol and Other Drug Dependence Treatment'' as ''CMS4.'' It should have read ''CMS137, 'Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.' ''

E. Medicare Shared Savings Program

As required under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). Please refer to the CY 2020 PFS proposed rule for a summary of policies finalized in prior rules (84 FR 40705).

As a general summary, in the CY 2020 PFS proposed rule, we:

- Discussed aligning the Shared Savings Program quality measure set with proposed changes to the Web Interface measure set under MIPS per previously-finalized policy;
- Proposed a change to the claims-based measures;
- Solicited comment on aligning the Shared Savings Program quality score with the MIPS quality performance category score; and
- Proposed a technical change to correct a cross-reference within a provision of the Shared Savings Program's regulations on the skilled nursing facility (SNF) 3-day rule waiver, to conform with amendments to § 425.612 that were adopted in the final rule for the Shared Savings Program that appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success; final rule) (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule'').

1. Quality Measurement

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the final rule establishing the Shared Savings Program that appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; final rue (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule''), we established a quality measure set spanning four domains: patient experience of care, care coordination/patient safety, preventive health, and at-risk population (76 FR 67872 through 67891). Since the Shared Savings

Program was established, we have updated the measures that comprise the quality performance measure set for the Shared Savings Program through the annual rulemaking in the CY 2015, 2016, 2017, and 2019 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, 81 FR 80484 through 80489, and 83 FR 59707 through 59715 respectively).

As we stated in the November 2011 final rule (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes. For performance years starting in 2019, 23 quality measures will be used to determine ACO quality performance (83 FR 59707 through 59715). The information used to determine ACO performance on these quality measures will be submitted by the ACO through the CMS Web Interface, calculated by us from administrative claims data, and collected via a patient experience of care survey referred to as the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey.

Eligible clinicians who are participating in an ACO and who are subject to MIPS (MIPS eligible clinicians) will be scored under the APM scoring standard under MIPS (81 FR 77260). These MIPS eligible clinicians include any eligible clinicians who are participating in an ACO in a track (or payment model within a track, such as Levels A–D of the BASIC Track) of the Shared Savings Program that is not an Advanced APM, as well as those participating in an ACO in a track (or payment model within a track) that is an Advanced APM, but who do not become Qualifying APM Participants (QPs) as specified in § 414.1425, and are not otherwise excluded from MIPS.

b. CMS Web Interface and Claims-Based Measures

Since the Shared Savings Program was first established in 2012, we have updated the quality measure set to reduce reporting burden and focus on more meaningful, outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2019 PFS final rule (83 FR 59711). In the CY 2019 PFS final rule, we explained that in developing the proposed changes to the quality measure set for 2019, we had considered the agency's efforts to streamline quality measures, reduce regulatory burden and promote innovation as part of the agency's Meaningful Measures initiative (*see* CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html*). We also noted that under the Meaningful Measures initiative, we have committed to assessing only those core issues that are most vital to providing high-quality care and improving patient outcomes, with the aim of focusing on high-priority measures, reducing unnecessary burden on providers, and putting patients first. The changes made in the CY 2019 PFS final rule reduced the Shared Savings Program quality measure set from 31 to 23 measures. Currently, more than half of the 23 Shared Savings Program quality measures are outcome and high-priority measures, including:

- Patient-experience of care measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience.
- Outcome measures supporting effective communication and care coordination, such as unplanned admission and readmission measures.
- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes.

As we stated in the CY 2019 PFS final rule (83 FR 59713), we seek to align the Shared Savings Program quality measure set with changes made to the CMS Web Interface measures under the Quality Payment Program. In the 2017 PFS final rule, we stated that we do not believe it is beneficial to propose CMS Web interface measures for ACO quality reporting separately (81 FR 80499). Therefore, to avoid confusion and duplicative rulemaking, we adopted a policy that any future changes to the CMS Web interface measures would be proposed and finalized through rulemaking for the Quality Payment Program, and that such changes would be applicable to ACO quality reporting under the Shared Savings Program. In accordance with the policy adopted in the CY 2017 PFS final rule (81 FR 80501), we did not make any specific proposals related to changes in CMS Web Interface measures reported under the Shared Savings Program in the CY 2020 PFS proposed rule (84 FR 40706). Rather, we referred readers to Appendix 1, Table C (Existing Quality Measures Finalized for Removal Beginning with the 2022 MIPS Payment Year) and Table Group A (New Quality Measures Finalized for Addition Beginning with the 2022 MIPS Payment Year) of the proposed rule for a complete discussion of the proposed changes to the CMS Web Interface measures for performance year 2020 (2022 MIPS Payment Year). As discussed in section III.I.3.B.1 of this final rule, no changes are being finalized to the CMS Web Interface measures set for performance year 2020. As a result, ACOs will continue to be responsible for reporting the following measure for performance year 2020 for purposes of the Shared Savings Program:

- ACO–14 Preventive Care and Screening Influenza Immunization

As explained in the proposed rule, we will maintain the measure with the ''substantive'' change described in Appendix 1, Table D–A 81 (Previously Finalized Quality Measures with Substantive Changes Finalized for the 2022 Payment Year and Future Years) of this final rule. As discussed in Table D–A 81 of this final rule, we have reviewed the ''substantive'' change and we do not believe this change to the measure would require that we revert the measure to pay-for-reporting for the 2020 performance year. We have determined that we can create a historical benchmark using data reported for the measure in past years as updating the numerator instructions that allow the use of the Live Attenuated Influenza Vaccine (LAIV) does not significantly impact ACO–14; but rather, allows for shared decision making between the patient and the eligible clinician over the best method of administration, while aligning with the current performance period's CDC/ACIP guidelines without negatively affecting clinicians providing LAIV.

Additionally, in section III.I.3.B.(1) of the CY 2020 PFS proposed rule, we proposed to add the following measure to the CMS Web Interface for purposes of the Quality Payment Program:

- *ACO–47 Adult Immunization Status:* We refer readers to Appendix 1, Table Group A.3 of this final rule for a discussion of comments received on this proposal. Based on the policies being finalized for purposes of MIPS in Appendix 1, Table Group A.3 of this final rule, Shared Savings Program ACOs will not be responsible for reporting the Adult Immunization Status measure (ACO–47) for performance year 2020.

In section III.J.3.c.(1)(d) of the CY 2020 PFS proposed rule, we discussed our determination, based on extensive stakeholder feedback, that the 2018 CMS Web Interface measure numerator guidance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (ACO–17) measure was inconsistent with the intent of the CMS Web Interface version

of this measure as modified in the CY 2018 Quality Payment Program final rule (82 FR 54164) and unduly burdensome on clinicians. We explained that, due to this numerator guidance, we were unable to rely on historical data to benchmark the measure. Therefore, for the 2018 performance year we explained that we were designating the measure pay-for-reporting in accordance with § 425.502(a)(5).

Additionally, in section III.J.3.c.(1)(d) of the CY 2020 PFS proposed rule, we proposed to update the CMS Web Interface measure numerator guidance for purposes of the Quality Payment Program. We noted that to the extent that this change would constitute a change to the Shared Savings Program measure set after the start of the 2019 performance period, we believed that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to modify the measure as proposed in Table DD because the guidance was inconsistent with the intent of the CMS Web Interface version of this measure, as modified in the CY 2018 Quality Payment Program final rule, and unduly burdensome on clinicians. We noted that if this modification were finalized as proposed, then consistent with our discussion in the CY 2018 PFS final rule, we expected that we would be able to use historical data reported on the measure to establish an appropriate 2019 benchmark that aligns with the updated specifications (82 FR 53214 and 53215) and the measure would be pay-for-performance for performance years starting in 2019 and all subsequent years.

While we did not make any specific proposals under the Medicare Shared Savings Program related to the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (ACO–17) measure for performance years starting in 2019, we did receive public comments on the proposed update to the numerator guidance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (ACO–17) measure for performance years starting in 2019. The following is a summary of the comments we received and our response.

Comment: Commenters unanimously supported the proposed update to the numerator guidance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (ACO–17) measure as discussed in Table DD in Appendix 1 of this final rule (Previously Finalized Quality Measures with Substantive Changes finalized for the 2021 MIPS Payment Year). However, commenters unanimously opposed CMS designating the measure to pay-for-performance for performance years starting in 2019. Several commenters expressed concerns that notice of this change for 2019 is coming late in the performance year, which they stated did not allow sufficient time for vendors and/or ACOs to update workflows and reports before the start of CMS Web Interface reporting and could have a negative impact on performance. As a result of these stated concerns, the commenters opposed reverting this measure to pay-for-performance and suggested it remain pay-for-reporting for 2019. Many commenters suggested that CMS keep the measure as pay-for-reporting for 2018 and 2019 consistent with our policy that newly introduced measures will be pay-for-reporting for 2 years, and another commenter expressed concern with the lack of clarity in the specifications which they stated would support maintaining the measure in a pay-for-reporting status for 2019 and 2020.

Response: We refer readers to Table DD.1 (Previously Finalized Quality Measures with Substantive Changes finalized for the 2021 MIPS Payment Year) for more details on the updated numerator guidance and measure specifications for ACO–17. We note that we did not make a proposal to make ACO–17 pay-for-performance for 2019; rather, we noted in the proposed rule that we were reverting the measure back to the version finalized in the CY 2018 PFS final rule and explained that we would have the data to create a benchmark for performance years starting in 2019, and thus the measure would be pay for performance. At that time, we had concluded that the ''substantive'' changes to this measure adopted in the CY 2018 PFS final rule would not require CMS to revert the measure to pay-for-reporting because we would still be able to use historical data reported on the measure to establish an appropriate benchmark that aligned specifications (82 FR 53214 and 53215). However, we understand commenters' concerns about changes to the specifications during the performance period and how these changes could potentially impact workflow.

We have been persuaded by commenters that scoring ACO–17 for performance years starting in 2019 could disadvantage clinicians who had planned to implement the measure with the revised numerator guidance that was in place for 2018. Reverting this measure to the version finalized for 2018 is considered a substantive change, as reflected in the CY 2018 Quality Payment Program final rule (82 FR 54164). The regulations at § 425.502(a)(5) grant CMS discretion to redesignate a measure as pay for reporting when there is a determination under the Quality Payment Program that the measure has undergone a substantive change. Accordingly, we are exercising that discretion to revert ACO–17 to pay for reporting for performance years starting in 2019. We believe that this will allow time for ACOs (and their vendors) to take the steps necessary to report the measure consistent with the specifications in performance year 2020. Accordingly, we are finalizing that ACO–17 will be pay-for-reporting for performance years starting in 2019, but will revert to pay-for-performance for performance year 2020.

In the CY 2020 PFS proposed rule, we noted that AHRQ, which is the measure steward for ACO–43—Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment), made an update to the measure that will require a change to the measure specifications for performance year 2020.[102] Currently, ACO–43 assesses the risk adjusted rate of hospital discharges for acute PQI conditions with a principal diagnosis of dehydration, bacterial pneumonia, and urinary tract infection. The updated measure will only include two conditions, bacterial pneumonia and urinary tract infection. This measure is a composite measure and the rate of hospital discharges is approximately equal to the sum of the rates of hospital discharges for each of its components. Therefore, the removal of dehydration will likely decrease the composite rate by approximately the rate of dehydration discharges. Based on this substantive change, we proposed to redesignate ACO–43 as pay-for-reporting for 2020 and 2021 consistent with our policy under § 425.502(a)(4), which provides that a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods the measure is required. However, we also considered creating a benchmark using historical data for bacterial pneumonia and urinary tract infection and keeping the measure pay-for-performance. As this is a claims-based measure, we have access to historical data for both bacterial pneumonia and urinary tract infection so we would be able to create a historical benchmark for the revised

[102] *https://www.qualityindicators.ahrq.gov/News/Retirement%20Notice_v2019_Indicators.pdf.*

measure. However, we also explained our belief that changes to measures can impact how ACOs, their ACO participants, and ACO provider/suppliers allocate their resources and redesign their care process to improve quality of care for their beneficiaries. As a result, we noted that our proposal to revert the measure to pay-for-reporting for 2 years would give ACOs time to refine care processes and educate clinicians while also gaining experience with the refined composite measure and an understanding of performance under revised benchmarks prior to the start of a pay for performance year.

We received public comments on this proposal and the alternative approach considered. The following is a summary of the comments we received and our response.

Comment: Commenters unanimously supported our proposal to revert the revised version of ACO–43—Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment) to pay-for-reporting for 2020 and 2021. The commenters agreed with CMS that this will give ACOs time to refine care processes and educate clinicians, while also gaining experience with the revised composite measure. One commenter stated that with only one of the two sub-measures (pneumonia) tested and endorsed at the facility level, it is not known how well the two components together represent the quality of the care provided by ACOs. The commenter suggested that CMS ensure the composite is tested at the ACO level and reviewed by NQF.

Response: We acknowledge the commenter's concern with regard to not knowing how well the revised two component measure will represent the quality of the care provided by the ACO; reverting the measure to pay-for-reporting for 2 years allows us to review/analyze performance data for the revised measure before incorporating the measure performance into the Shared Savings Program quality score.

After considering the comments received we are finalizing our proposal that ACO–43—Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment) will be pay-for-reporting for 2020 and 2021 consistent with our policy under § 425.502(a)(4), which provides that a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods the measure is required.

Table 40 shows the Shared Savings Program quality measure set for performance year 2020 and subsequent performance years that will result from the finalized policies in section III.I.3.B.(1) of this final rule.

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TABLE 40: Measure Set for Use in Establishing the Shared Savings Program Quality Performance Standard, Starting with Performance Year 2020

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		NQF N/A AHRQ	Survey	R	P	P
	ACO - 2	CAHPS: How Well Your Providers Communicate		NQF N/A AHRQ	Survey	R	P	P
	ACO - 3	CAHPS: Patients' Rating of Provider		NQF N/A AHRQ	Survey	R	P	P
	ACO - 4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ	Survey	R	P	P
	ACO - 5	CAHPS: Health Promotion and Education		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 6	CAHPS: Shared Decision Making		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 7	CAHPS: Health Status/Functional Status		NQF #N/A AHRQ	Survey	R	R	R
	ACO - 34	CAHPS: Stewardship of Patient Resources		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 45	CAHPS: Courteous and Helpful Office Staff		NQF #N/A AHRQ	Survey	R	R	P
	ACO - 46	CAHPS: Care Coordination		NQF #N/A AHRQ	Survey	R	R	P
Care Coordination/ Patient Safety	ACO - 8	Risk-Standardized, All Condition Readmission		Adapted NQF #1789 CMS	Claims	R	R	P
	ACO - 38	Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions		NQF#2888 CMS	Claims	R	R	P
	ACO - 43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment)	✓	AHRQ	Claims	R	R	P
	ACO - 13	Falls: Screening for Future Falls		NQF #0101 NCQA	CMS Web Interface	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO-14	Preventive Care and Screening: Influenza Immunization		NQF #0041 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 18	Preventive Care and Screening: Screening for Depression and Follow-up Plan		NQF #0418 CMS	CMS Web Interface	R	P	P
	ACO - 19	Colorectal Cancer Screening		NQF #0034 NCQA	CMS Web Interface	R	R	P
	ACO - 20	Breast Cancer Screening		NQF #2372 NCQA	CMS Web Interface	R	R	P
	ACO - 42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease		NQF #N/A CMS	CMS Web Interface	R	R	R

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance		
						PY1	PY2	PY3
Clinical Care for At Risk Population - Depression	ACO - 40	Depression Remission at Twelve Months		NQF #0710 MNCM	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Diabetes	ACO-27	Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%))		NQF #0059 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension : Controlling High Blood Pressure		NQF #0018 NCQA	CMS Web Interface	R	P	P

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The net result of the final policies in section III.I.3.b.(1) of this final rule will be a set of 23 measures on which ACOs' quality performance will be assessed for performance year 2020 and subsequent performance years. The 4 domains will include the following numbers of quality measures (See Table 41):

- Patient/Caregiver Experience of Care-10 measures.
- Care Coordination/Patient Safety-4 measures.
- Preventive Health-6 measures.
- At Risk Populations-3 measures.

Table 41 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes.

TABLE 41: Number of Measures and Total Points for Each Domain within the Shared Savings Program Quality Performance Standard, Starting with Performance Year 2020

Domain	Number of Individual Measures	Total Measures for Scoring Purposes	Total Possible Points	Domain Weight
Patient/Caregiver Experience	10	10 individual survey module measures	20	25%
Care Coordination/ Patient Safety	4	4 measures	8	25%
Preventive Health	6	6 measures	12	25%
At-Risk Population	3	3 individual measures	6	25%
Total in all Domains	23	23	46	100%

c. Solicitation of Comment on Aligning the Shared Savings Program Quality Score With the MIPS Quality Score

As discussed above, our principal goal in selecting quality measures for the Shared Savings Program has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes. The Shared Savings Program quality measure set currently consists of 23 measures spanning four domains that are submitted by the ACO through the CMS Web Interface, calculated by us for ACOs from administrative claims data, and collected via a patient experience of care survey referred to as the CAHPS for ACOs Survey. The number of measures within the four domains has changed over time to reflect changes in clinical practice, move towards more outcome and high-priority measures, align with other quality reporting programs, and reduce burden; however, the overall structure of four equally weighted measure domains has remained consistent in determining ACOs' quality performance since the Shared Savings Program was established in 2012. As provided in section 1899(d)(2) of the Act and § 425.502(a) of the Shared Savings Program regulations, ACOs must meet a quality performance standard to qualify to share in savings. Currently, the quality performance standard is based on an ACO's performance year rather than financial track. The quality performance standard is defined at the level of full and complete reporting (pay-for-reporting (P4R)) for the first performance year of an ACO's first agreement period. In the second or subsequent years of the first agreement period and all years of subsequent agreement periods, quality measures are scored as pay-for-performance (P4P) according to the phase-in schedule for the specific measure and the ACO's performance year in the Shared Savings Program:

- For all performance years, ACOs must completely and accurately report all quality data used to calculate and assess their quality performance.
- CMS designates a performance benchmark and minimum attainment level for each P4P measure and establishes a point scale for the measure. An ACO's quality performance for a measure is evaluated using the appropriate point scale, and these measure specific scores are used to calculate the final quality score for the ACO.
- ACOs must meet minimum attainment (defined as the 30th

percentile benchmark for P4P measures) on at least one measure in each domain to be eligible to share in any savings generated (§ 425.502(d)(2)(iii)(A)).

ACOs are rewarded for their quality performance on a sliding scale on which higher levels of quality performance translate to higher rates of shared savings and, depending on the track under which an ACO is participating, may result in lower rates of shared losses. In addition, ACOs that demonstrate significant quality improvement on measures in a domain are eligible to receive a quality improvement reward (§ 425.502(e)(4)). Specifically, for each domain, ACOs can be awarded up to four additional points for quality performance improvement on the quality measures within the domain. These bonus points are added to the total points that an ACO achieves for the quality measures within that domain, but the total number of points cannot exceed the maximum total points for the domain.

In the CY 2018 Quality Payment Program final rule, we finalized a policy for the 2018 performance period and subsequent performance periods that the quality performance category under the MIPS APM Scoring Standard for MIPS eligible clinicians participating in a Shared Savings Program ACO will be assessed based on measures collected through the CMS Web Interface and the CAHPS for ACOs survey measures (82 FR 53688 through 53706). We assign the same MIPS quality performance category score to each Tax Identification Number (TIN)/National Provider Identifier (NPI) in a Shared Savings Program ACO based on the ACO's total quality score derived from the measures reported via the CMS Web Interface and the CAHPS for ACOs survey. Eligible clinicians in a Shared Savings Program ACO will receive full credit for the improvement activities performance category in 2020 based on their performance of improvement activities required under the Shared Savings Program. In addition, ACO participants report on the Promoting Interoperability performance category at the group or solo practice level for eligible clinicians subject to the Promoting Interoperability performance category. Data for the Promoting Interoperability performance category is reported by ACO participants at the TIN level and is then weighted and aggregated to get a single ACO score for the performance category that applies to all eligible clinicians participating in the ACO. These three categories in the APM scoring standard are weighted as follows: Quality is 50 percent, Improvement Activities is 20 percent; and Promoting Interoperability is 30 percent. Eligible Clinicians participating in the Shared Savings Program are not assessed under the MIPS cost performance category as these eligible clinicians are already subject to cost and utilization performance assessments as part of the Shared Savings Program. Therefore, the cost performance category is weighted at zero percent.

Eligible clinicians who reassign their billing rights to an ACO Participant TIN in an Advanced APM (Track 2, Track 1+ ACO Model, BASIC Track Level E, and ENHANCED Track (formerly known as Track 3)) and who are included on the Advanced APM Participation List on at least one of three snapshot dates (March 31, June 30, and August 31) during the performance year may become Qualifying APM Participants (QPs) for the year, if they meet payment or patient count thresholds. If these eligible clinicians attain QP status for the performance year via their participation in the Shared Savings Program ACO, they would receive an APM incentive payment and would not be subject to the MIPS reporting requirements or payment adjustment for the related payment year. However, they would be required to report quality for purposes of the Shared Savings Program financial reconciliation.

As we explained in the CY 2020 PFS proposed rule (83 FR 40710), we recognize that ACOs and their participating providers and suppliers have finite resources to dedicate to engaging in efforts to improve quality and reduce costs for their assigned beneficiary population. Although CMS has worked to align policies under the Shared Savings Program with the Quality Payment Program, we recognize that some differences in program methodologies for the Shared Savings Program and MIPS remain and could potentially create conflicts for MIPS eligible clinicians in an ACO who are attempting to strategically transform their respective practices to earn shared savings under the terms of the Shared Savings Program and a positive payment adjustment under MIPS. Currently, under the Shared Savings Program, ACOs in performance years other than the first performance year of their first agreement period are allocated up to two points for quality measures that are pay-for-performance, according to where their performance falls, relative to benchmark deciles. Incomplete reporting of any CMS Web Interface measure will result in zero points for all CMS Web Interface measures and the ACO will fail to meet the quality performance standard for the performance year. Similarly, if a CAHPS for ACOs Survey is not administered and/or no data is transmitted to CMS, zero points will be earned for all Patient/Caregiver Experience measures and the ACO will fail to meet the quality standard for the performance year. The quality measure set for the Shared Savings Program also includes certain claims-based measures that are not part of the MIPS quality performance category, and we currently calculate performance rates on these claims-based measures for purposes of determining an ACO's overall quality score under the Shared Savings Program.

In contrast, when a group submits measures for the MIPS quality performance category via the CMS Web Interface, each measure is assessed against its benchmark to determine how many points the measure earns. For the 2019 MIPS performance period, a group can receive between 3 and 10 points for each MIPS measure (not including bonus points) that meets the data completeness and case minimum requirements by comparing measure performance to established benchmarks. If a group fails to meet the data completeness requirement on one of the CMS Web Interface measures, it receives zero points for that measure; however, all other CMS Web Interface measures that meet the data completeness requirement are assessed against the measure benchmarks, and the points earned across all measures are included in the quality performance category score. Currently, the only administrative claims-based measure used in MIPS is the All-Cause Readmission measure, which is only calculated for groups with 16 or more eligible clinicians. These differences between the Shared Savings Program quality measure set and the MIPS quality measure set highlight the different quality measurement approaches for which Shared Savings Program ACOs must simultaneously evaluate, prioritize, and target resources that may be better directed toward patient care if the quality measurement approaches under the Shared Savings Program and MIPS were more closely aligned.

As we stated in the proposed rule, we believe that using a single methodology to measure quality performance under both the Shared Savings Program and the MIPS would allow ACOs to better focus on increasing the value of healthcare, improving care, and engaging patients, and reduce burden as ACOs would be able to track to a smaller measure set under a unified scoring methodology. Accordingly, we solicited comment on how to potentially align the Shared Savings Program

quality reporting requirements and scoring methodology more closely with the MIPS quality reporting requirements and scoring methodology.

We received public comments on how to potentially align the Shared Savings Program quality reporting requirements and scoring methodology more closely with the MIPS quality reporting requirements and scoring methodology. The following is a summary of the comments we received and our response.

Comment: Several commenters supported the concept of aligning the Shared Savings Program quality score with the MIPS quality performance category scoring methodology in the interest of reducing program complexity and reporting burden. One commenter suggested that CMS consider alignment opportunities and approaches holistically rather than compartmentalized within programs; as MIPS Value Pathways (MVPs) are also intended to reduce burden and confusion and align metrics, the commenters encouraged CMS to explore opportunities to systematically address changes to both the Shared Savings Program and MIPS in a coordinated fashion. Another commenter was generally supportive of alignment between Medicare programs but expressed concern that ACOs are already navigating a complete overhaul of the program under the new policies established in the December 2018 Pathways to Success final rule (83 FR 67816). The commenter stated that quality reporting and scoring is one of the few areas of consistency in the Shared Savings Program and now is not the time to overhaul these quality requirements in the midst of all the other changes to which ACOs are adjusting.

The majority of commenters were opposed to the approach of aligning the Shared Savings Program quality score with the MIPS quality performance category score. Commenters stated that ACOs are focused on the total population they serve and accountable for total costs of caring for their aligned beneficiary population. The commenters stated that ACOs should have a separate quality measure set and methodology for scoring quality, thus keeping the MIPS quality performance category score separate from the assessment of the quality performance of ACOs under the Shared Savings Program. Several commenters suggested that CMS should test the use of a more limited number of quality measures with low reporting burdens, including eCQMs and claims-based measures designed specifically for ACOs, which they believed would be appropriate for organizations committed to population health and accountable for total cost of care for the patients they serve. Several commenters noted that aligning the Shared Savings Program quality score with the MIPS quality performance category score would increase burden and require resources that would be better directed to improve patient care but did not elaborate on why they believed this approach would be more burdensome. Another commenter stated that while they appreciate the sentiment to keep quality measurement and scoring simple and aligned across programs, the measures used in APMs, such as the Shared Savings Program, should lead and not follow MIPS because the quality measure sets used in MIPS continue to be populated with specialty driven measures, which the commenter believed do not encourage transition to APMs. Another commenter stated that the goals of the two programs may not lend themselves to perfect alignment as the MIPS program is specialty and provider specific, making episodic measures more meaningful, whereas ACOs are responsible for beneficiaries' total cost of care over the course of the entire performance year and it stands to follow that eligible clinicians participating in ACOs should be accountable for total health measures.

Several commenters that opposed the concept of alignment of the Shared Savings Program quality score with the MIPS quality performance category score also stated that a significant restructuring of the Shared Savings Program quality performance requirements would introduce more confusion for ACOs that are transitioning into new pathway tracks, as well as uncertainty, as CMS has also proposed extensive revisions to MIPS as the program transitions to MIPS Value Pathways. Another commenter stated they disagreed with replacing the Shared Savings Program quality score with the MIPS quality performance category score until such a time that CMS can ensure that the measures and patient populations included are aligned across both programs. The commenter stated that MIPS uses a retrospective approach to assign patients to individual clinicians or practices, whereas, the commenter stated, Shared Savings Program uses a prospective approach to assign beneficiaries to ACOs. Because of these differences, the commenter believed replacing the Shared Savings Program quality score with the MIPS quality performance category score would lead to inconsistent and incorrect comparisons.

Response: As we plan for future updates and changes to the Shared Savings Program quality reporting requirements and scoring methodology, we will consider this feedback in the development of our proposals.

In particular, we requested comments on replacing the Shared Savings Program quality score with the MIPS quality performance category score, for ACOs in Shared Savings Program tracks (or payment models ~~levels~~ within a track) that do not meet the definition of an Advanced APM (currently, Track 1 and BASIC Track Levels A, B, C and D). We explained that allowing for a single quality performance score for both programs would eliminate the need for ACOs to focus their resources for quality improvement on maximizing performance under two separate quality reporting requirements with distinct scoring methodologies. Currently, for ACOs in tracks (or payment models within a track) that do not meet the definition of an Advanced APM, the MIPS quality performance category score is calculated based on the measures reported by the ACO via the CMS Web Interface and the CAHPS for ACO survey measures. For Shared Savings Program quality scoring purposes, we indicated that we could utilize the MIPS quality performance category score, converted to a percentage of points earned out of the total points available, as the ACO's quality score for purposes of financial reconciliation under the Shared Savings Program. Since the release of the proposed rule, we have updated the MIPS Quality performance category scores for 2018, and we note that for performance year 2018, the weighted mean MIPS quality performance category score for ACOs in Shared Savings Program tracks (or payment models within a track) that do not meet the definition of an Advanced APM was 48.16 and the weighted median MIPS quality performance score for these ACOs was 50.00, out of a possible 50 points assigned for the quality performance category.

ACOs in tracks (or payment models within a track) that meet the definition of an Advanced APM whose eligible clinicians are QPs for the year and thus are excluded from the MIPS reporting requirements, do not receive a quality performance category score under MIPS. Instead the quality data the ACO reports to the CMS Web Interface is used along with the ACO's CAHPS data and the administrative claims-based measures calculated by us, solely for the purpose of scoring the quality performance of the

ACO under the Shared Savings Program quality scoring methodology. As an alternative, given that we currently collect the necessary data from these ACOs, we explained that we could also calculate a quality score for these ACOs under the MIPS scoring methodology, and use this score to assess the quality performance of the ACO for purposes of the Shared Savings Program. Using this score would also inform eligible clinicians participating in these ACOs of their MIPS quality score in the event that they lose QP status and are scored under the MIPS APM scoring standard.

Utilizing a MIPS quality performance category score to assess the quality performance for purposes of the Shared Savings Program of ACOs in tracks (or payment models within a track) that qualify as an Advanced APM would not change whether eligible clinicians participating in the ACO obtain QP status and are excluded from MIPS, nor would it change the ACO participant TINs' eligibility to receive Advanced APM incentive payments. Rather, under this approach we would utilize the same scoring methodology to determine quality performance for Shared Savings Program ACOs that are participating in Advanced APMs as would be used to assess the quality performance of ACOs in Shared Savings Program tracks (or payment models within a track) that do not meet the definition of an Advanced APM, creating further alignment of performance results and further synergies between the Shared Savings Program and MIPS.

We welcomed public comments on the approach of using the MIPS quality performance category score to assess quality performance for purposes of the Shared Savings Program quality performance standard for ACOs that are in tracks (or payment models within a track) that qualify as Advanced APMs, and therefore, do not receive a MIPS quality performance category score if their eligible clinicians meet QP or Partial QP thresholds and are excluded from MIPS, as well as potential alternative approaches for scoring Shared Savings Program quality performance in a way that more closely aligns with MIPS. The following is a summary of the comments we received and our response.

Comment: We received few comments specifically on the approach of using the MIPS quality performance category score to assess quality performance for purposes of the Shared Savings Program quality performance standard for ACOs that are in tracks (or payment models within a track) that qualify as Advanced APMs. Some commenters supported the approach, stating that increased alignment with the MIPS scoring methodology would provide more comparable data and lessen the burden for eligible clinicians. Another commenter supported the approach of using MIPS quality scores as the Shared Savings Program quality performance score, stating that this approach would simplify the process for eligible clinicians participating in the Shared Savings Program, including eligible clinicians participating in Advanced APMs that do not meet the criteria to be a QP and reduce the complexity and burden of reporting.

One commenter did not support the approach of using the MIPS quality performance category score to assess quality performance for purposes of the Shared Savings Program quality performance standard for ACOs that are in tracks (or payment models within a track) that qualify as Advanced APMs because they support the current methodology, which they believed focuses on the total cost of care, not just the physician service component.

Response: As we plan for future updates and changes to the Shared Savings Program quality scoring methodology, we will consider this feedback in the development of our proposals.

In addition, we also solicited comment on simplifying MIPS by implementing a new MIPS Value Pathway framework, which may include implementing a core measure set using administrative claims-based measures that can be broadly applied to communities or populations and developing measure sets around specialty areas or public health conditions to standardize and provide more cohesive reporting and participation. We refer readers to section III.I.3.a.(3) of this final rule for more information on these approaches and a summary of the comments received.

Currently, for ACOs in tracks (or payment models within a track) that do not meet the definition of an Advanced APM, the MIPS quality performance category score is calculated based on the measures reported by the ACO via the CMS Web Interface and the CAHPS for ACO survey measures. In section III.I.3.b.(1)(ii) of the proposed rule, we proposed to add the MIPS All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions (MCC) measure to the MIPS quality performance category. We noted that if this measure were to be added to MIPS quality performance category, implementation of the measure would be delayed until the 2021 performance period for MIPS. We explained that if the MCC measure were to be included in the MIPS quality performance category, we would also consider including the MIPS claims-based measures (MCC and MIPS All-Cause Readmission measure) in the MIPS APM scoring standard for ACOs in tracks (or payment models within a track) that are not Advanced APMs and in the MIPS quality performance category equivalent score for ACOs in tracks that are Advanced APMs, in order to fully align the quality scoring methodology under the Shared Savings Program with the MIPS scoring methodology to reduce the burden on ACOs and their eligible clinicians of tracking to multiple quality reporting requirements and quality scoring methodologies. We would then use this score for purposes of assessing quality performance under the Shared Savings Program for all ACOs. We noted that these MIPS claims-based measures are similar to those currently used to assess ACO quality under the Shared Savings Program. The MIPS MCC and ACO MCC are similar because they both target patients with multiple chronic conditions but the cohort, outcome, and risk model for the MIPS MCC measure would vary from the ACO MCC measure. The cohort for the ACO MCC includes eight conditions whereas the MIPS MCC measure includes nine conditions, where the additional condition is diabetes. The ACO MCC measure does not adjust for social risk factors whereas the MIPS MCC measure adjusts for two area-level social risk factors: (1) AHRQ socioeconomic status (SES) index; and (2) specialist density. We referred readers to Appendix 1 Table AA (New Quality Measures for Addition for the 2023 Payment Year and Future Years) of the proposed rule for more detailed information on the MIPS MCC measure. Both the MIPS and Shared Savings Program versions of the All-Cause Readmission measure were developed to fully align with the original hospital measure of Hospital-Wide Readmission. The MIPS and Shared Savings Program versions of the All Cause Readmission measure are essentially re-specifications of the same hospital measure and are updated annually to maintain that alignment. Because of this, the measures have a very similar, or identical, definition for included patients, outcome definition, and risk adjustment model. The primary difference between the measures is only the entity that is accountable—either an ACO or a MIPS-eligible clinician—but the specifications are otherwise aligned. We noted that we welcomed comment on potentially including all of the MIPS claims-based measures in the MIPS

quality performance category score (instead of the 3 claims-based measures that are currently included in the Shared Savings Program quality score), and using this score (converted to a percentage of points earned out of the total points available) in place of the current Shared Savings Program quality score to assess quality performance for all ACOs for purposes of the Shared Savings Program. We noted that we would also continue to assess ACOs on the CAHPS for ACOs survey but quality performance would be calculated by MIPS based on the methodology used for scoring the CAHPS for MIPS survey and included in the MIPS quality performance category score. The scoring and benchmarking approach for the CAHPS for MIPS is to assign points based on each summary survey measure (SSM) and then average the points for all the scored SSMs to calculate the overall CAHPS score. In contrast, ACOs currently, receive up to 2 points for each of the 10 SSMs for a total of 20 points.

We received several public comments on potentially including the CMS Web Interface, CAHPS for ACO survey and the two MIPS claims-based measures in the MIPS quality performance category score for ACOs and using this score in place of the current Shared Savings Program quality score to assess quality performance for all ACOs for purposes of the Shared Savings Program. The following is a summary of the comments we received and our response.

Comment: One commenter supported the use of a sparing list of meaningful measures that reduce the burden of reporting and applauded CMS' efforts to seek out opportunities for greater harmonization and streamlining within FFS Medicare and across programs. Another commenter urged CMS to review the measures it includes in the Shared Savings Program measure set, as well as other Medicare Programs and models, because the current measures are not clinically appropriate or applicable to a frail, seriously ill, or home-limited patient population. The commenter stated they were concerned that even though they were delivering high-quality and clinically appropriate care to this medically complex patient population, they are penalized under these initiatives. However, the majority of commenters opposed to this approach. One commenter stated that the All Cause Unplanned Admissions for Patients with Multiple Chronic Conditions would be difficult for ACOs to manage due to all the included conditions. The commenter added that ACOs do not receive enough actionable data in the quality reports provided by CMS to fully understand their performance on the measure. The commenter suggested providing the number of patients included in the numerator and in the denominator and identifying the actual patients that were included would give providers more actionable information. A few commenters expressed concern that any consideration of aligning the Shared Savings Program quality scoring methodologies with the MIPS quality score when CMS is also beginning significant modifications to the MIPS program introduces a great deal of uncertainty regarding how the quality scoring methodology may also change in the future; therefore, they do not believe the MIPS All-Cause Readmission and MCC claims-based measures would be appropriate for ACOs. Another commenter stated that they do not believe the MIPS administrative claims-based measures are a better alternative to the administrative claims-based measures ACOs are currently subject to. The commenter noted that ACOs are responsible for the total cost of care for their aligned beneficiary populations; therefore, CMS must use a different approach in evaluating the quality of care furnished ACOs as compared to individuals or groups reporting quality measures in MIPS, who are not participating in total cost of care.

Response: As we plan for future updates and changes to the Shared Savings Program quality scoring methodology, we will consider this feedback in the development of our proposals.

In addition, we solicited comment on determining the threshold for minimum attainment in the Shared Savings Program using the MIPS APM quality performance category scoring. As noted previously in this section, ACOs in the first performance year of their first agreement period are considered to have met the quality performance standard, and therefore, to be eligible to share in savings or minimize shared losses, if applicable, when they completely and accurately report all quality measures. ACOs in all other performance years are required to completely and accurately report and meet the minimum attainment level on at least one measure in each domain, to be determined to have met the quality performance standard and to be eligible to share in savings. For these ACOs, minimum attainment is defined as a score that is at or above 30 percent or the 30th percentile of the performance benchmark. The 30th percentile for the Shared Savings Program is the equivalent of the 4th decile performance benchmark under MIPS APM quality performance category scoring. We indicated that as we look to more closely align with MIPS quality performance category scoring in future years, we were considering how to determine whether ACOs have met the minimum attainment level. For example, minimum attainment could continue to be defined as complete and accurate reporting for ACOs in their first performance year of their first agreement period, while a MIPS quality performance category score that is at or above the 4th decile across all MIPS quality performance category scores would be required for ACOs in all other performance years under the Shared Savings Program. ACOs with quality scores under the 4th decile of all MIPS quality performance category scores would not meet the quality performance standard for the Shared Savings Program and thus would not be eligible to share in savings or would owe the maximum shared losses, if applicable. In addition, ACOs with quality scores under the 4th decile of all MIPS quality performance category scores would be subject to compliance actions and possible termination. We acknowledged that a requirement that ACOs achieve an overall MIPS quality performance category score (or equivalent score) that meets or exceeds the 4th decile across all MIPS quality performance category scores would be a higher standard than the current requirement that ACOs meet the 30th percentile on one measure per Shared Savings Program quality domain; however, section 1899(b)(3)(C) of the Act not only gives us discretion to establish quality performance standards for the Shared Savings Program, but also indicates that we should seek to improve the quality of care furnished by ACOs over time by specifying higher standards. We believe that increasing the minimum attainment level would incentivize improvement in the quality of care provided to the beneficiaries assigned to an ACO. Furthermore, consistent with section 1899(b)(3)(C) of the Act, it is appropriate to require a higher standard of care in order for ACOs to continue to share in any savings they achieve. Given the maturity of the Shared Savings Program, we are also considering setting a higher threshold, such as the median or mean quality performance category score across all MIPS quality category scores, for determining eligibility to share in savings under the Shared Savings Program for all ACOs, other than those ACOs in their first performance year of their first agreement period. We welcomed comment on these potential approaches or other approaches for determining Shared Savings Program

quality minimum attainment using MIPS data.

We also solicited comment on how to potentially utilize the MIPS quality performance category score to adjust shared savings and shared losses under the Shared Savings Program, as applicable. Currently, for all Shared Savings Program ACOs and Track 1+ Model ACOs, the ACO's quality score is multiplied with the maximum sharing rate of the track to determine the final sharing rate, and therefore, the amount of shared savings, if applicable. For some ACOs under two-sided models, specifically ACOs in Track 2 and the ENHANCED track, the ACO's quality score is also used in determining the amount of shared losses owed, if applicable. Under Track 2 and the ENHANCED track, the loss sharing rate is determined as 1 minus the ACO's final sharing rate based on quality performance, up to a maximum of 60 percent or 75 percent, respectively. Under the Track 1+ Model and two-sided models of the BASIC track (Levels C, D and E), the amount of shared losses is determined based on a fixed 30 percent loss sharing rate, regardless of the ACO's quality score. Thus, a higher quality score results in the ACO receiving a higher proportion of shared savings in all Shared Savings Program tracks and the Track 1+ Model, or greater mitigation of shared losses in Track 2 and the ENHANCED track. We stated that we could apply the MIPS quality performance category score to determine ACOs' shared savings and shared losses, if applicable, in the same manner. For instance, as an alternative to the current approach to determining shared savings payments for Shared Savings Program ACOs, we could establish a minimum attainment threshold, such as a score at or above the 4th decile of all MIPS quality performance category scores or the median or mean quality performance category score, that if met would allow ACOs to share in savings based on the full sharing rate of their track. We welcomed comment on these or other potential approaches for utilizing the MIPS quality performance category score or an alternative score in determining shared savings or shared losses under the Shared Savings Program.

In addition, we discussed an option considered under which we would determine the MIPS quality performance category score for all Shared Savings Program ACOs as it is currently calculated for non-ACO group reporters using the CMS Web Interface. That is, ACOs would receive a score for each of the measures they report and zero points for those measures they do not report. This would be a change from the current methodology under which ACOs must report all Web Interface measures to complete quality reporting. We noted that currently, for ACOs in the first year of their first agreement period, minimum attainment is set at the level of complete and accurate reporting of all measures. If we were to adopt the MIPS quality performance category score as the Shared Savings Program quality score, we would consider no longer imposing a different quality standard for ACOs in the first year of their first participation agreement versus ACOs in later performance years. Given that the Shared Savings Program is evolving and many Medicare quality programs including MIPS are incentivizing performance rather than reporting, we noted that we are considering no longer transitioning from pay-for-reporting to pay-for-performance during an ACO's first agreement period in the Shared Savings Program. We stated that we believe requiring all ACOs regardless of time in the program to be assessed on quality performance would be an appropriate policy since nearly 100 percent of ACOs consistently satisfactorily report all quality measures. We welcomed comment on this alternative for determining the MIPS quality performance category score.

We received public comments on determining the threshold for minimum attainment in the Shared Savings Program using the MIPS APM quality performance category scoring and the approach of scoring ACOs for each measure they report and zero points for those measures they do not report. The following is a summary of the comments we received and our response.

Comment: One commenter noted that using the MIPS scoring methodology for ACOs would result in a somewhat higher standard than is currently used because ACOs would need to meet a minimum overall threshold rather than a threshold on one measure in each domain to be eligible to share in savings. However, the commenter noted that ACOs would benefit by being able to earn a quality score even if they fail to report one measure. The commenter stated the benefits of this approach outweigh the drawbacks and supported the option of aligning the Shared Savings Program quality scoring methodology with the current methodology used for MIPS. This commenter also stated that under this alternate approach ACOs should be able to proceed directly to pay-for-performance, particularly since failure on one measure would no longer result in overall failure in quality performance.

The majority of commenters opposed the approach of determining the threshold for minimum attainment in the Shared Savings Program using the MIPS APM quality performance category scoring. Several commenters stated that they did not support the option of using a MIPS quality scoring approach that would hold ACOs to a higher standard to be eligible to share in savings, if earned, by requiring a quality performance score at or above the fourth decile across all MIPS quality performance category scores in order to meet the minimum attainment level. These commenters also stated that they were concerned the MIPS quality scoring methodologies could result in narrow bands for measures with clustered performance, resulting in inequitable scores for very small differences in performance especially when extrapolated from a small sample size. They offered an example under which small differences in measure performance rates might result in measure point changes that could add up quickly and may not reflect substantive differences in actual quality of care. The commenters stated their belief that percentile rankings are more meaningful because they provide the larger context and help appropriately adjust the actual scores. Another commenter stated that if the goal is to align the Shared Savings Program and MIPS quality scoring approaches, then it would make little sense to hold ACOs to a higher attainment standard than other MIPS clinicians; they suggested setting the minimum attainment standard for ACOs at the 3rd decile rather than the 4th decile. Another commenter opposed increasing the minimum attainment standard under the Shared Savings Program stating their belief that the current Shared Savings Program quality scoring methodology is sufficient to incentivize high quality care. The commenter also stated that ACOs enter the program with differing levels of performance on the Shared Savings Program quality measures and different levels of experience documenting quality metrics in a manner required by the program. In addition, the commenter expressed the belief that it takes time to implement new workflows to maximize performance, so increasing the minimum attainment level could act as a deterrent to new entrants joining the program or ACOs remaining in the program and working to improve care. Several commenters expressed concerns about the concept of removing the pay-

for-reporting year currently provided to ACOs in their first year of their first agreement, stating that this change would have significant repercussions for new ACOs. The commenters noted that providing ACOs in their first year with 12 months to assess performance, understand measure specifications, and implement workflow and IT changes necessary to capture data and document quality performance as specified by the measure steward is a vast undertaking requiring significant resources. In addition, the commenters stated this time is crucial to educate clinicians and support staff to incorporate processes to implement the quality measure requirements into their practice and establish buy-in and support among staff.

Response: As we plan for future updates and changes to the Shared Savings Program quality scoring methodology, we will consider this feedback in the development of our proposals.

Lastly, we solicited comment on using the MIPS quality improvement scoring methodology rather than the Shared Savings Program Quality Improvement Reward to reward ACOs for quality improvement. Under the Shared Savings Program, we currently allow ACOs not in their first performance year in the program to earn a Quality Improvement Reward in each of the four quality domains. In contrast, under MIPS, improvement points are generally awarded as part of the MIPS quality performance category score if a MIPS eligible clinician (1) has a quality performance category achievement percent score for the previous performance period and the current performance period; (2) fully participates in the quality performance category for the current performance period; and (3) submits data under the same identifier for the 2 consecutive performance periods. As a result, if we were to adopt an approach under which we use the MIPS quality performance category score for the Shared Savings Program quality score, quality improvement points earned under MIPS would be included in that score, and we would not have a need to add additional points to it. We welcomed public comment on this or other approaches to considering improvement as part of using the MIPS quality performance category or an equivalent score, to determine quality performance under the Shared Savings Program.

We received no public comments on using the MIPS quality improvement scoring methodology rather than the Shared Savings Program Quality Improvement Reward to reward ACOs for quality improvement.

2. Technical Change To Correct Reference in SNF 3-Day Rule Waiver Provision

In the December 2018 final rule, we made a number of amendments to § 425.612 (83 FR 68080). As part of these amendments, we redesignated paragraphs (a)(1)(v)(A) through (C) of § 425.612 as paragraphs (a)(1)(v)(C) through (E). In making these amendments, we inadvertently omitted a necessary update to a cross-reference to one of these provisions. Accordingly, we propose to remove the phase ''paragraph (a)(1)(v)(B)'' from § 425.612(a)(1)(v)(E), and in its place add the phrase ''paragraph (a)(1)(v)(D)''.

We received no public comments on this proposal, and are finalizing the technical change as proposed.

F. Open Payments

1. Background

a. Open Payments Policies

The Open Payments program is a statutorily-mandated program that promotes transparency by providing information to the public about the financial relationships between the pharmaceutical and medical device industry, and certain types of health care providers. Section 1128G of the Act requires manufacturers of covered drugs, devices, biologicals, or medical supplies (referred to as ''applicable manufacturers''), as well as group purchasing organizations (GPOs), to annually submit information for the preceding calendar year about certain payments or other transfers of value made to ''covered recipients,'' currently defined as physicians and teaching hospitals.

Payments or other transfers of value that must be reported include such things as research, honoraria, gifts, travel expenses, meals, grants, and other compensation. The type of information required to be reported includes, but is not limited to, the date and amount of the payment or other transfer of value, identifying information about the covered recipient, and details about products associated with the transaction. When a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological or medical supply, the name of that covered drug, device, biological or medical supply also must be reported. The estimated burden of these reporting requirements, as outlined under OMB control number 0938–1237, is just over 1 million hours over the course of 1 year.

Section 1128G of the Act establishes certain minimum dollar thresholds for required reporting, with two bases for reporting: Individual and aggregate payments; or transfers of value. To determine if small individual payments or other transfers of value made to a covered recipient exceed the aggregate threshold and must be reported, applicable manufacturers and applicable GPOs must aggregate all individual payments made across all payment categories within a given reporting year. The statutory threshold established in 2013 was $10 for individual payments, and $100 for aggregated payments, and this amount has increased with the consumer price index each year. For CY 2019, the annual reporting thresholds for individual payments or other transfers of value is $10.79 and the aggregate amount is $107.91.

The Open Payments program yields information to the general public that may influence their health care decision-making and choice of providers, as well as information that researchers may use to look into potential correlations between financial relationships and provider behaviors. More than 64 million records have been disclosed under the Open Payments program since August 2013, enabling significant transparency into covered exchanges of value. We have been committed to stakeholder engagement in an effort to limit burden in the Open Payments program reporting processes and improve clarity for the public. Additional background about the program and guidance, including frequently asked questions, about how the program works and what type of information is required to be reported is available at *www.cms.gov/OpenPayments.*

In the February 8, 2013 **Federal Register** (78 FR 9458), we issued regulations implementing section 1128G of the Act to create the Open Payments program. Section 1128G of the Act requires applicable manufacturers and applicable GPOs to submit information annually about certain payments or other transfers of value made to covered recipients during the course of the preceding calendar year. Additionally, section 1128G of the Act defines covered drugs, devices, biologicals, or medical supplies as those covered under Medicare, a State plan under Medicaid, or the Children's Health Insurance Program (CHIP) (or a waiver of either such state plan), and requires applicable manufacturers and applicable GPOs to disclose any ownership or investment

interests in such entities held by physicians or physician's immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Under section 1128G(e)(10)(A) of the Act, the term ''payment or other transfer of value'' refers to a transfer of anything of value, though some exclusions apply.

In the CY 2015 PFS final rule with comment period (79 FR 67548), we revised the regulations by standardizing reporting in the Open Payments program. Specifically, we: (1) Deleted the definition of ''covered device''; (2) removed the special rules for payments or other transfers of value related to continuing education programs; (3) clarified the marketed name reporting requirements for devices and medical supplies; and (4) required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.

In the CY 2017 PFS proposed rule (81 FR 46395), we solicited information from the public on a wide variety of information regarding the Open Payments program. Since the implementation of the program and changes made in the CY 2015 PFS final rule with comment period, various commenters have provided us feedback. Consequently, we identified areas in the rule that might benefit from revision and solicited public comments to inform future rulemaking. We sought comment on whether the nature of payment categories listed at § 403.904(e)(2) are adequately inclusive to facilitate reporting of all payments or transfers of value, as well as ways to streamline or make the reporting process more efficient while facilitating our role in oversight, compliance, and enforcement, along with posing other program-specific questions. A summary of solicited comments was published in the CY 2017 PFS final rule (81 FR 80428–80429).

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–270) was signed into law. Section 6111 of the SUPPORT Act amended the definition of ''covered recipient'' under section 1128G(e)(6) of the Act with respect to information required to be submitted on or after January 1, 2022, to include physician assistants (PA), nurse practitioners (NP), clinical nurse specialists (CNS), certified registered nurse anesthetists (CRNA), and certified nurse midwives (CNM), in addition to the previously listed covered recipients of physicians and teaching hospitals. In the CY 2020 PFS proposed rule, we proposed to codify the Open Payments provisions from the SUPPORT Act, proposed to address public comments received from the CY 2017 PFS proposed rule by simplifying the process for reporting data by adjusting the nature of payment categories, and proposed changes to standardize data on reported covered drugs, devices, biologicals, or medical supplies.

b. Legal Authority

Three principal legal authorities from the Social Security Act ground our provisions:

- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1861 of the Act, which defines providers and suppliers.
- Section 1128G of the Act, as amended by section 6111 of the SUPPORT Act, which requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare or a State plan under Medicaid or CHIP to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals, and to PAs, NPs, CNSs, CRNAs, and CNMs for information required to be submitted under section 1128G of the Act on or after January 1, 2022.

c. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

In the CY 2020 PFS proposed rule, we proposed to revise several Open Payments regulations at 42 CFR part 403. We proposed that the following provisions be effective for data collected beginning in CY 2021 and reported in CY 2022: (1) Expanding the definition of a covered recipient to include the categories specified in the SUPPORT Act; (2) expanding the nature of payment categories; and (3) standardizing data on reported covered drugs, devices, biologicals, or medical supplies. We also proposed a correction to the national drug codes (NDCs) reporting requirements for drugs and biologicals that, once finalized will be effective 60 days following the publication of the final rule. We believe this will give all stakeholders sufficient time to prepare for these requirements.

(1) Expanding the Definition of a Covered Recipient

Section 1128G of the Act requires applicable manufacturers and applicable GPOs to report annually information about certain payments or other transfers of value made to covered recipients, as well as ownership or investment interests held by physicians or their immediate family members in such entities. (Section 1128G(e)(7) of the Act exempts physicians who are employed by the reporting manufacturer, such that manufacturers do not report payments to their own employees.) As we noted previously, section 6111 of the SUPPORT Act expanded the definition of covered recipients from physicians and teaching hospitals to include PAs, NPs, CNSs, CRNAs, and CNMs; it likewise expanded to these individuals the same exception for manufacturer-employment. The SUPPORT Act requires these changes to be in effect for information required to be submitted on or after January 1, 2022. In short, the statute requires applicable manufacturers to report transfers of value pertaining to these additional provider types in the same way they have been required to report transfers of value to physicians and teaching hospitals. Since the information is reported to CMS in the calendar year following the year in which it was collected, this means that the data would be collected by the industry during CY 2021.

We proposed to revise § 403.902 to align with the statutory requirements in sections 1128G(e)(6)(A) and (B) of the Act. Specifically, we proposed to revise the definition of ''covered recipient'' in § 403.902 to include PAs, NPs, CNSs, CRNAs, and CNMs. In addition, we proposed at § 403.902 to reference the definitions of these additional provider types as defined in sections 1861(aa)(5)(A), (aa)(5)(B), (bb) (2), and (gg)(2) of the Act.

We also proposed to update certain provisions in part 403, subpart I to include provider and supplier types other than physicians as specified in sections 1128G(e)(6)(A) and (B) of the Act. Specifically, we proposed the following revisions:

- In § 403.902, to add the definitions of ''certified nurse midwife,'' ''certified registered nurse anesthetist,'' ''clinical nurse specialist,'' ''non-teaching hospital covered recipient,'' ''nurse practitioner,'' and ''physician assistant.''
- In § 403.902, to revise the definition of ''covered recipient'' by adding physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse-midwife'' after the phrase ''Any physician.''
- In § 403.904(c)(1), (f)(1)(i)(A), and (h)(7), to replace the term ''physician'' with the phrase ''non-teaching hospital.''

• In § 403.904(c)(3), to replace the term ''physician'' in the title with the phrase ''non-teaching hospital,'' add the phrase ''non-teaching hospital'' after ''In the case of a,'' and remove the phrase ''who is a physician'' from the text.

• In § 403.904 (c)(3)(ii) and (iii), (f)(1)(i)(A)(*1*), (f)(1)(i)(A)(*3*) and (*5*), and (f)(1)(v), to change the term ''physician'' to the phrase ''non-teaching hospital covered recipient.''

• In § 403.904(h)(13), to remove the phrase ''who is a physician'' and add the phrase ''non-teaching hospital'' after ''In the case of.''

• In § 403.904(f)(1), to remove the phrase ''(either physicians or teaching hospitals).''

• In § 403.908(g)(2)(ii), to change the words ''physicians and teaching hospitals'' to the term ''Covered recipients.''

The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed support for the expansion of the definition of covered recipients.

Response: We thank the commenters for their support.

Comment: Some commenters asked about the definitions of covered recipients. A subset asked how the definition of the new covered recipient categories will be consistent across jurisdictions and recommended partnering with stakeholders to ensure appropriate solutions. Another asked that definitions be consistent throughout CMS guidance documents.

Response: While we appreciate these questions, the definitions for the additional covered recipients are delineated within the SUPPORT Act and will be the same across all jurisdictions or regions. The SUPPORT Act directly references the definitions of the service providers within existing statute (section 1861 of the Act). Since our proposal was designed to implement the provisions of the SUPPORT Act with regard to the definition of covered recipients, we believe providing the definitions within the statute is sufficient, and at § 403.902, we proposed to add these definitions verbatim from the statute. We will continue to work with stakeholders to determine the challenges that the industry may face and to work through the best solutions available to implement a robust program. We are committed to providing sufficient guidance to reporting entities regarding how to properly identify covered recipients when submitting data for the new categories prior to implementing this change. As we update our technical assistance and guidance, we will continue to provide clarifications requested through our outreach and education. The Open Payments help desk will continue to be available for direct questions. A summary of comments received pertaining to the validation of data on the new covered recipient categories is provided below.

Comment: One commenter asked whether updated templates will be provided for data submission.

Response: We expect to update the submission templates based on changes made in this rule, and they will be made available prior to the start of data collection for CY 2021 data, which will be submitted in CY 2022. While we assume that this question related to the covered recipient provision, the answer holds true for the other Open Payments provisions as well.

Comment: Some commenters suggested that CMS extend Open Payment deadlines. Other commenters requested delays for reporting data, noting that it may not be possible to arrange and capture all the new information about the new covered recipients in CY 2021 by the CY 2022 annual reporting deadline. Another requested extending the time period for review, dispute, and correction.

Response: As mentioned earlier, this rule was designed specifically to implement the provisions of the SUPPORT Act regarding covered recipients in the Open Payments program. Therefore, the effective date(s) we proposed are based on the statute, and we do not have the authority to alter the statutory requirement.

Comment: Some commenters suggested that it would facilitate prompt and complete reporting if CMS would provide technical support for implementation of the new provisions.

Response: We will continue to provide technical support through direct outreach, outreach to associations, the issuance of guidance, informational webinar sessions, and direct assistance via the program help desk. We intend to continue to operate as a responsible business partner in this manner.

Comment: Some commenters raised concerns with ensuring the integrity of the reported data from submission through the review and dispute process, to the subsequent publication of the data given the new covered recipient provider types.

Response: The Open Payments program has a system in place for reporting entities to include unique identifying information about covered recipients, such as an NPI or state license number, when submitting a record. We understand that accurately identifying mid-level practitioners will entail additional challenges. As we have in the past, we will work with stakeholders to understand the challenges the new covered recipient categories may impose, and collaborate on practical solutions that ensure accuracy and availability of necessary data. We will also provide technical assistance to reporting entities to help them accurately report on the additional covered recipients. The review and dispute process is set forth in regulation at § 403.908(g) and upholds the reporting standards that are in the statute at 42 U.S.C. 1320a–7h (c)(1)(C) and (D). We follow the guidelines in the regulation to ensure timely publication of data, and we do not have the authority to modify a statutory provision. We will provide outreach and technical support through the issuance of guidance, informational webinar sessions, and direct assistance via the program help desk as it has throughout the implementation of the Open Payments program. Furthermore, we annually revise and republish reports with any data that has been updated throughout the year. In addition to our direct outreach to covered recipients, we encourage industry groups to reiterate the opportunities that covered recipients have to review and verify data that have been reported under their name.

Comment: One commenter asked CMS to simplify the two-step registration process for covered recipients. Another commenter suggested that additional disclaimers should be provided with the Open Payments data noting that payments or transfers of value do not necessarily imply wrongdoing. One commenter suggested that CMS require each reporting entity to have a direct point of contact for covered recipients to contact to help resolve disputed claims. Another commenter suggested that NPIs be collected and included in the Open Payments datasets, noting that this would assist in matching and cross-referencing data. Two other commenters recommended expanding the Open Payments program. One suggested it cover all forms of potential conflicts of interest in the medical community; another suggested it cover venture capital companies that purchase physician practices.

Response: While we appreciate these suggestions, they are outside the scope of this rule.

After consideration of these comments, we are finalizing our proposed revisions to §§ 403.902, 403.904, and 403.908.

(2) Nature of Payment Categories

Under current statutory and regulatory requirements, applicable manufacturers and applicable GPOs must characterize the nature of payments made to covered recipients by selecting the ''Nature of Payment'' category that most closely describes the reported payment. Some of the ''Nature of Payment'' categories, as specified at § 403.904(e)(2), are specifically required by section 1128G(a)(1)(A)(vi) of the Act, while the statute also allows the Secretary to define any other nature of payment or other transfer of value.

Based upon information we obtained from the public comments solicited in the CY 2017 PFS proposed rule (81 FR 46395), stakeholders have identified debt forgiveness, long term medical supply or device loan, and acquisitions (among others) as useful categories to add to comply with the general reporting requirement under section 1128G(a)(1)(A) of the Act. Therefore, and so as to add clarity to the types of payments or transfers of value made by applicable manufactures and applicable GPOs to covered recipients, we proposed to revise the ''Nature of Payment'' categories in § 403.904(e)(2) by consolidating two duplicative categories and by adding the three new categories described below.

First, the categories that we proposed to consolidate include two separate categories for continuing education programs. Section 1128G(a)(1)(A)(vi)(XIII) of the Act requires manufacturers to report direct compensation for serving as faculty or a speaker for medical education programs. The current § 403.904(e)(2)(xiv) and (xv) distinguish between accredited/certified and unaccredited/non-certified continuing education programs. Although we defined separate categories at the inception of the Open Payments program, we no longer believe that the distinction in this category is necessary. In revised § 403.904(e)(2)(xv), we proposed to consolidate these categories and make the regulatory wording match the statutory language ''medical education programs,'' which we believe would streamline the reporting requirements while not detracting from the underlying context of the data.

In addition, we proposed three additional categories that would operate prospectively and would *not* require the updating of previously reported payments or other transfers of value that may fall within these new categories.

The three new categories are as follows:

- *Debt Forgiveness* (§ 403.904(e)(2)(xi)): This will be used to categorize transfers of value related to forgiving the debt of a covered recipient, a physician owner, or the immediate family of the physician who holds an ownership or investment interest.
- *Long-Term Medical Supply or Device Loan* (new § 403.904(e)(2)(xiv)): Section 403.904 currently contains an exclusion from reporting for the loan of a covered device, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days, or a quantity of 90 days of average use, respectively. This new category will be used to characterize the loans of covered devices or the provision of medical supplies for longer than 90 days. (*Note:* We proposed to combine current paragraphs on continuing education programs § 403.904(e)(2)(xiv) and (xv) to replace paragraph (e)(2)(xv) as noted in the consolidating continuing education programs above.)
- *Acquisitions* (§ 403.904(e)(2)(xviii)): This addition will provide a category for characterizing buyout payments made to covered recipients in relation to the acquisition of a company in which the covered recipient has an ownership interest.

We also proposed to add the definition of ''long-term medical supply or device loan'' to § 403.902 as ''the loan of supplies or a device for 91 days or longer.'' For consistency within the definitions section, we proposed to redesignate § 403.904(h)(5), which contains the definition of ''short-term medical supply or device loan'' to § 403.902. As a result, we proposed a new § 403.904(h)(5) to be ''short-term medical supply or device loan.''

We received several comments regarding our proposed revisions to the nature of payment categories. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported the nature of payment changes.

Response: We thank the commenters for their support.

Comment: One commenter disagreed with the consolidation of the faculty or speaker compensation for continuing education programs because they believe that the difference between accredited/certified and unaccredited/non-certified is significant in potential manufacturer influence. Another commenter suggested that honoraria for continuing medical education presenters should be excluded.

Response: By aligning to the terminology provided in the statute, we are streamlining data reporting. We do not believe that the change to ''medical education programs''—without differentiating whether they are accredited/certified—will detract from the context of the data (that is, being paid by a manufacturer to be on the faculty or speak at medical educational programs). Generally speaking, direct or indirect payments or other transfers of value for serving as a faculty or speaker at a medical education program would be reportable under Open Payments unless an exclusion applies.

Comment: Two commenters suggested that clarification be provided on what would be covered in the consolidated nature of payment category ''medical education programs'' to ensure programs for the expanded group of covered recipients are covered in the same way as physicians.

Response: We consider this term to be broad enough to encompass various types of education programs, regardless of whether separate covered recipient groups may describe them with different names. We will keep this feedback in mind as we develop our operational guidance on the implementation of this provision.

Comment: Some commenters requested additional information and guidance on what types of payments and transfers of value would fall within the nature of payment categories.

Response: As part of the rulemaking process, we provided definitions for the new categories in the proposed rule to be codified at § 403.902. As part of the Open Payments operations, further technical assistance and operational guidance will be provided. We will provide technical support through direct outreach, outreach to associations, the issuance of guidance, informational webinar sessions, as well as direct assistance via the program help desk as we have offered consistently throughout the implementation of the Open Payments program.

Comment: Some commenters recommended revising the definition of the nature of payment category ''education'' to exclude materials such as medical journal articles.

Response: Although we appreciate this suggestion, it is outside the scope of this rule.

After considering the aforementioned comments discussed here and in the covered recipients provision regarding our proposed changes to the nature of payment provision, we are finalizing the changes proposed in §§ 403.902 and 403.904.

(3) Standardizing Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies

When applicable manufacturers or applicable GPOs report payments or

transfers of value related to specific drugs and biologicals, we currently require names and NDCs to be reported to the Open Payments program. Since there was a lack of federally-recognized medical device identifiers (DIs) when we started the Open Payments program, we have not required analogous reporting for the manufacturers of such devices. However, the Food and Drug Administration (FDA) established and continues to implement a system for the use of standardized unique device identifiers (UDIs) for medical devices and has issued regulations at 21 CFR part 801, subpart B, and 21 CFR part 830, requiring, among other things, that a UDI be included on the label of most devices distributed in the United States. (See 78 FR 58785, September 24, 2013.) Based upon the FDA's UDI regulatory requirements and the requirement by the HHS Office of the National Coordinator for Health Information Technology (ONC) that UDIs form part of the Common Clinical Data Set (45 CFR part 170), we believe that the use of UDIs and DIs, a subcomponent of the UDI, have become more standardized. Moreover, the HHS Office of Inspector General (OIG) included a recommendation for Open Payments to require more specific information about devices in an August 2018 report (OEI–03–15–00220).[103]

With the standardization and typical use of UDIs and based upon OIG's recommendation, we proposed that the DI component, the mandatory fixed portion of the UDI assigned to a device, if any, should be incorporated into Open Payments reporting that applicable manufacturers or applicable GPOs provide. We did not propose to require a full UDI. We believe the step that we proposed would substantially aid in enhancing the quality of the Open Payments data because the identifiers could be used to validate submitted device information. This effort will also enhance the usefulness of Open Payments data to the public by providing more precise information about the medical supplies and devices associated with a transaction. Specifically, we proposed to revise § 403.904(c)(8) to require applicable manufacturers and applicable GPOs to provide the DIs (if any) to identify reported devices in a comprehensive fashion meaningful to the users of Open Payments data and reorganize the section accordingly.

We also sought to further clarify the reporting requirements with regard to drugs and biologicals. Since the outset of the Open Payments program, NDCs have been required for both research and non-research payments. In § 403.904(f)(1)(iv), we require that NDCs be reported for drugs and biologicals used in research. However, in the CY 2015 PFS final rule with comment period (79 FR 67548), the non-research payment NDC requirement was erroneously removed when changes were made to the rule text regarding marketed names. We proposed to correct this error in order to reiterate that NDCs are required for both research and non-research payments and to make the change effective 60 days from publishing the final rule.

We proposed to revise § 403.904(c)(8) to require DIs (if any) to identify reported devices in a comprehensive fashion meaningful to the users of Open Payments data and reorganize the section accordingly. We also proposed to reincorporate language that specifically required reporting of NDCs.

As a result of the changes to § 403.904(c)(8), we also proposed technical changes to § 403.904(f)(1)(iv) and to add mirrored definitions from 21 CFR 801.3 for ''device identifier'' and ''unique device identifier'' to § 403.902.

We received comments regarding our proposed revisions to standardize data on reported covered drugs, devices, biologicals, or medical supplies. The following is a summary of the comments we received and our responses.

Comment: Some commenters provided their support for adding DIs to the data being reported. Commenters believe that this will make the data more useful to the public.

Response: We thank the commenters for their support.

Comment: Some commenters suggested removing or delaying the addition of DIs to the data being collected. The commenters raised concerns about scenarios in which multiple DIs could be associated with one transaction or a device may be associated with multiple identifiers. Commenters stated that reporting would be cumbersome to manufacturers and that the subsequent data may be confusing to the public.

Response: We look forward to discussing the details of implementation solutions with stakeholders. As noted in the proposed rule, part of the value of collecting DIs is that we believe such a step would substantially aid in enhancing the quality of the Open Payments data because the DIs can be used to validate submitted device information, such as the marketed or brand name. Our intention is to provide meaningful data to the public; therefore, we hope stakeholders will continue to contribute to our process as we move to update our data systems. As part of the Open Payments operations technical assistance, we will provide guidance, explanations, and examples of how to report DIs, as well as how to report when there are multiple DIs, to industry on our website and through other outreach efforts. We will also provide technical support through direct outreach, outreach to industry groups, the issuance of guidance, informational webinar sessions, and direct assistance via the program help desk. As noted in the proposed rule, we proposed that this provision be effective for data collected beginning in CY 2021 and reported in CY 2022, and we believe that this will give all stakeholders sufficient time to prepare for these requirements.

Comment: One commenter recommended that the following additional data items be collected from reporting entities and made available: (1) Whether it is a manufacturer or GPO; (2) If it is a manufacturer, what it produces; and (3) If it is a GPO, whether it is a physician owned distributor (POD). Another commenter recommended that CMS assess penalties on PODs that do not comply with the statute by accurately and completely reporting payments or transfers of value to covered recipients. Finally, one commenter suggested that DIs be added to all claims data.

Response: While we appreciate these suggestions, they are outside the scope of this rule.

Comment: One commenter suggested increasing the monetary threshold for reporting.

Response: While we appreciate this suggestion, it is outside the scope of this rule. Additionally, we note that the monetary threshold is set in statute at 42 U.S.C. 1320a–7h(e)(10)(B)(i), and therefore, we do not have the authority to make the suggested change.

After considering the other Open Payments comments and the above comments on standardizing data, we are finalizing the changes proposed in §§ 403.902 and 403.904.

G. Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior To Furnishing Home Infusion Therapy

Section 5012 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255; enacted December 13, 2016) created a separate Medicare Part B benefit under section 1861(s)(2)(GG) and section 1861(iii) of the Act to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously

[103] The HHS OIG report OEI–03–15–002200 is available at *https://oig.hhs.gov/oei/reports/oei-03-15-00220.pdf.*

or subcutaneously through a pump that is an item of durable medical equipment in the beneficiary's home, effective for January 1, 2021. Section 5012 of the Cures Act also added section 1834(u) to the Act, which establishes the payment and related requirements for home infusion therapy under this benefit. Section 1834(u)(6) of the Act requires that, prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan of care described in section 1861(iii)(1) of the Act shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

We recognize there are several possible forms, manners, and frequencies that physicians may use to notify patients of their infusion therapy treatment options. For example, a physician may verbally discuss the treatment options with the patient during the visit and annotate the treatment decision in the medical record before establishing the infusion plan. Some physicians may also provide options in writing to the patient in the hospital discharge papers or office visit summaries, as well as retain a written patient attestation that all options were provided and considered. The frequency of discussing these options could vary based on a routine scheduled visit or according to the individual's clinical needs.

We solicited comments in the CY 2020 PFS proposed rule (84 FR 40716), as well as the CY 2020 HH PPS proposed rule (84 FR 34694), regarding the appropriate form, manner, and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy (home or otherwise) under Medicare Part B. We also invited comments on any additional interpretations of this notification requirement.

The following is a summary of the comments received on both solicitations.

Comment: Several commenters supported the proposed examples of the physician verbally discussing the infusion therapy options and annotating the resulting decision in the medical record and initial plan of care. Many commenters stated that written materials may be a helpful supplement to a verbal conversation, but written materials should not be the sole means of beneficiary notification. They emphasized that infusion therapy options should be verbally discussed so the patient, and any family caregiver, may have an opportunity to get immediate answers to questions that may not be addressed in written materials. Many commenters encouraged CMS to consider minimizing the paperwork burden and confusion that written documents or patient attestations could impose on physicians and patients.

Commenters recommended that the conversation should include how the infusion therapy options differ in terms of effectiveness, safety, time, comfort, convenience, location, frequency, and out-of-pocket costs. Some commenters specifically noted that beneficiaries are subject to the standard 20 percent coinsurance with this new Part B benefit; and the ordering physician should be aware of the patient's insurance status, and therefore, assist them in making informed decisions about their care.

Some commenters recommended the policy should allow for other professionals, such as social workers, home health nurses, and other staff to assist the treating physician with this notification in order to remove unnecessary administrative burden for clinicians. Commenters also requested the notification policy include requirements that are simple and easy for physicians to implement, and would retain the current flexibility for physicians to use multiple notification mechanisms as directly suggested by beneficiaries, advocates and stakeholders.

One commenter requested that CMS follow similar procedures for other electronically prompted beneficiary notifications. Another commenter recommended that CMS develop a single standardized format for this notice to avoid benefit denials and delays in therapy. Another commenter suggested that CMS establish a training program for physicians, hospitals and contractors prior to implementation.

One commenter requested that CMS permit sufficient time for physicians to research the available home infusion therapy options. Another commenter requested that CMS create a web page where a beneficiary or referring clinician can research if there is a home infusion therapy supplier in the beneficiary's geographic location that is capable of delivering these services, and that the supplier is enrolled and approved by Medicare.

Two commenters requested that this notification be required only when the drug regimen is available and appropriate for home infusion therapy. They suggested that notification should not be required if there are certain safety risks associated with infusion therapy in that patient's home or if the home infusion therapy option is not available in the patient's geographic area.

Regarding the frequency of notification, one commenter suggested that only one streamlined notice be required at the start of therapy because many therapies have a duration for the life of the beneficiary. Two commenters specified that notification of options should be discussed and documented in the patient record whenever a new infusion therapy treatment is deemed necessary by the physician and anytime thereafter if there are changes in patient condition or circumstances that would affect the patient's choices.

Response: We appreciate the commenters' support and recommendations and will take the comments into consideration as we continue developing future policy through notice-and-comment rulemaking effective for home infusion therapy services beginning CY 2021 and for subsequent years.

H. Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

1. Enrollment of Opioid Treatment Programs

a. Legislative and Regulatory Background

As previously explained in this final rule, the SUPPORT Act was designed to alleviate the nationwide opioid crisis by: (1) Reducing the abuse and supply of opioids; (2) helping individuals recover from opioid addiction and supporting the families of these persons; and (3) establishing innovative and long-term solutions to the crisis. Section 2005 of the SUPPORT Act attempts to fulfill these objectives, in part, by establishing a new Medicare benefit category for opioid treatment programs (OTPs). Section 2005(d) of the SUPPORT Act amended section 1866(e) of the Act by adding a new paragraph (3) thereto that classified OTPs as Medicare providers (though only for the furnishing of opioid use disorder treatment services). This will enable OTPs that meet all applicable statutory and regulatory requirements to bill and receive payment under the Medicare program for furnishing such services to Medicare beneficiaries.

b. Definition of and Certain Requirements for OTPs

As already mentioned, an OTP is currently defined in 42 CFR 8.2 as a

program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1). Section 2005(b) of the SUPPORT Act added a new section 1861(jjj)(2) to the Act defining an OTP as an entity that meets, among other things, the definition of an OTP in § 8.2 (or any successor regulation). Section 1861(jjj)(2) of the Act also outlines certain additional requirements that an OTP must meet to qualify as such. These requirements include the following:

(1) Accreditation

Consistent with new section 1861(jjj)(2)(C) of the Act, as added by section 2005(b) of the SUPPORT Act (and also required under 42 CFR 8.11(a)(2)), an OTP must have a current, valid accreditation by an accrediting body or other entity approved by the Substance Abuse and Mental Health Services Administration (SAMHSA), the federal agency that oversees OTPs. A core purpose of OTP accreditation is to ensure that an OTP meets: (1) Certain minimum requirements for furnishing medication-assisted treatment (MAT); and (2) the applicable accreditation standards of SAMHSA-approved accrediting bodies, of which there presently are six. The accreditation process includes, but is not limited to, an accreditation survey, which involves an onsite review and evaluation of an OTP to determine compliance with applicable federal standards.

(2) Certification

A second requirement addressed in section 1861(jjj)(2)(B) of the Act, as added by section 2005(b) of the SUPPORT Act, is also outlined in current regulations referenced in § 8.11(a). Along with accreditation, an OTP must have a current, valid certification by SAMHSA for such a program. The prerequisites for certification (as well as the certification process itself) are addressed in § 8.11 and include, but are not restricted to, the following:

- Current and valid accreditation (as described previously);
- Adherence to the federal opioid treatment standards described in § 8.12; and
- Compliance with all pertinent state laws and regulations, as stated in § 8.11(f)(1).

Under § 8.11(a)(3), certification is generally for a maximum 3-year period, though this may be extended by 1 year if an application for accreditation is pending. SAMHSA may revoke or suspend an OTP's certification if any of the applicable grounds identified in § 8.14(a) or (b), respectively, exist. According to SAMHSA statistics, there are currently about 1,677 active OTPs; of these, approximately 1,585 have full certifications and 92 have provisional certifications.

(3) OTP Enrollment

Section 2005(b) of the SUPPORT Act, which added a new section 1861(jjj)(2)(A) to the Act, requires that an OTP be enrolled in the Medicare program under section 1866(j) of the Act to: (1) Qualify as an OTP; and (2) bill and receive payment from Medicare for opioid use disorder treatment services. Per section 1861(jjj)(2)(A) of the Act, and as discussed in more detail in this section III.H. of this final rule, we proposed a number of requirements in the CY 2020 PFS proposed rule that OTPs must meet to enroll in Medicare.

c. Current Medicare Enrollment Process

(1) Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help ensure that providers and suppliers that seek to bill the Medicare program for services or items furnished to Medicare beneficiaries are qualified to do so under federal and state laws. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. CMS and our Medicare Administrative Contractors (MACs; hereafter occasionally referred to as ''contractors'') carefully and closely screen and review Medicare enrollment applicants to verify that they meet all applicable legal requirements.

CMS has taken various steps via regulation to outline a process for enrolling providers and suppliers in the Medicare program. For instance, in the April 21, 2006 **Federal Register** (71 FR 20754), we published the ''Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment'' final rule that set forth certain requirements in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570) that providers and suppliers must meet to obtain and maintain Medicare billing privileges. We cited therein sections 1102 and 1871 of the Act as general authority for our establishment of these requirements, which were designed for the efficient administration of the Medicare program. Subsequent to the April 21, 2006 final rule, we published additional provider enrollment regulations. These were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against problematic providers and suppliers.

(2) Form CMS–855—Medicare Enrollment Application

Under § 424.510, a provider or supplier must complete, sign, and submit to its assigned MAC the appropriate Form CMS–855 (OMB Control No. 0938–0685) application in order to enroll in the Medicare program and obtain Medicare billing privileges. The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532; [104] Provider Enrollment, Chain, and Ownership System), captures information about the provider or supplier that is needed for CMS or its MACs to determine whether the provider or supplier meets all Medicare requirements. Data collected on the Form CMS–855 is carefully reviewed and verified by CMS or its MACs and includes, but is not limited to:

- General identifying information (for example, legal business name, tax identification number).
- Licensure and/or certification data.
- Any final adverse actions (as that term is defined in § 424.502) of the provider or supplier, such as felony convictions, exclusions by the HHS Office of Inspector General (OIG), or state license suspensions or revocations.
- Practice locations and other applicable addresses of the provider or supplier.
- Information regarding the provider's or supplier's owning and managing individuals and organizations and any final adverse actions those parties may have.

After receiving a provider's or supplier's application for initial enrollment, reviewing and confirming the information thereon, and determining whether the provider or supplier meets all applicable Medicare requirements, CMS or the MAC will either: (1) Approve the application and grant billing privileges to the provider or supplier (or, depending upon the provider or supplier type involved, simply recommend approval of the application and refer it to the state agency or to the CMS regional office, as

[104] *https://www.hhs.gov/foia/privacy/sorns/09700532/index.html.*

applicable); or (2) deny enrollment under § 424.530.

d. OTP Enrollment Provisions

(1) Legal Basis and Necessity

In proposing requirements and procedures with which OTPs must comply to enroll and remain enrolled in Medicare, we relied on the authority granted to us not only under section 1861(jjj)(2)(A) of the Act but also under several other statutory provisions. First, section 1866(j) of the Act provides specific authority with respect to the enrollment process for providers and suppliers. Second, sections 1102 and 1871 of the Act furnish general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

We believe, and it has been our longstanding experience, that the provider enrollment process is invaluable in helping to ensure that: (1) All potential providers and suppliers are carefully reviewed for compliance with all applicable requirements; (2) problematic providers and suppliers are kept out of Medicare; and (3) beneficiaries are protected from unqualified providers and suppliers. Indeed, without this process, the Medicare program and Medicare beneficiaries could be endangered, and billions of Trust Fund dollars could be paid to unqualified or fraudulent parties.

However, we noted in the proposed rule that our general concerns were not restricted to the mere need and desire to establish provider enrollment requirements for OTPs. While provider enrollment is a crucial component of CMS' overall broader program integrity efforts, it is not the only one. We emphasized that in establishing and implementing an overall Medicare OTP process per the SUPPORT Act and implementing an overall program integrity strategy, our objectives would extend to matters such as: (1) Monitoring OTP billing patterns; (2) ensuring the proper payment of OTP claims; (3) performing OTP audits as required by law; (4) making certain that OTP beneficiaries receive quality care; and (5) taking action (enrollment-related or otherwise) against non-compliant or abusive OTP providers. In other words, it should not be assumed for purposes of the OTP process that the term ''program integrity'' is limited to the provider enrollment concept, for it applies to many other types of payment safeguards as well.

(2) OTP Enrollment Requirements—Proposed Provisions in the CY 2020 PFS Proposed Rule

We proposed the following OTP enrollment provisions:

(a) Addition of § 424.67 and General OTP Requirement To Enroll

We proposed to establish a new § 424.67 that would include most of our OTP enrollment provisions. In paragraph (a) thereof, we proposed that for a program or eligible professional (as that term is defined in section 1848(k)(3)(B) of the Act) to receive Medicare payment for the provision of opioid use disorder treatment services, the provider must qualify as an OTP (as that term is defined in § 8.2) and enroll in the Medicare program under the provisions of part 424, subpart P, as well as the provisions of § 424.67.

(b) OTPs—Procedures and Compliance

In paragraph (b) of § 424.67, we proposed several specific enrollment requirements that OTPs must meet that either clarify or supplement those contained in subpart P.

(i) OTPs: Form CMS–855B

In § 424.67(b)(1), we proposed that an OTP must complete in full and submit the Form CMS–855B application (''Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers'') (OMB Control No.: 0938–0685) and any applicable supplement or attachment thereto (which would be submitted to OMB under control number 0938–0685) to its applicable Medicare contractor. The supplement or attachment would capture certain information that is: (1) Unique to OTPs but not obtained via the Form CMS–855B; and (2) necessary to enable CMS to effectively screen their applications and confirm their qualifications.

As part of this general requirement concerning Form CMS–855 completion, we proposed two subsidiary requirements as part of the aforementioned supplement/attachment.

First, in § 424.67(b)(1)(i), we proposed that the OTP must maintain and submit to CMS (via the applicable supplement/attachment) a list of all physicians and other eligible professionals (as the term ''eligible professional'' is defined in section 1848(k)(3)(B) of the Act) who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP. The list must include the physician's or other eligible professional's first and last name and middle initial, Social Security Number, National Provider Identifier, and license number (if applicable). We believed that this requirement would enable us to: (1) Confirm that these individuals are qualified to perform the activities in question; and (2) screen their prescribing practices, the latter being an especially important consideration in light of the nationwide opioid epidemic.

Second, we proposed in § 424.67(b)(1)(ii) that the OTP must certify via the Form CMS–855B and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in § 424.67(b) and (d) (discussed below).

(ii) OTPs: Application Fee

Under § 424.514, prospective and revalidating institutional providers that are submitting an enrollment application generally must pay the required application fee. (For CY 2019, the fee amount is $586.) Section 424.502 defines an institutional provider as any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and nonphysician practitioner (NPP) organizations, which are exempt from the fee requirement if they are enrolling as a physician or NPP organization), Form CMS–855S, Form CMS–20134, or an associated internet-based PECOS enrollment application. Since an OTP, as a specialized facility, would be required to complete the Form CMS–855B to enroll in Medicare as an OTP (and would not be enrolling as a physician or non-physician organization), we believed that an OTP would meet the definition of an institutional provider under § 424.502. Therefore, we proposed to clarify in new § 424.67(b)(2) that the OTP must pay an application fee consistent with § 424.514.

(c) OTPs: Categorical Risk Designation

Section 424.518 outlines enrollment screening categories and requirements based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the level of scrutiny with which CMS will screen and review providers or suppliers within that category.

There are three categories of screening in § 424.518: High, moderate, and limited, with the ''high'' category being the strictest level of screening. We proposed to include newly enrolling OTPs within this ''high'' classification. This means that the OTP would be

subject to the same screening procedures that apply to all other enrolling providers and suppliers (regardless of the risk category into which they fall) as well as the following:

- A site visit.
- Submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.
- A fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.

We generally explained that a high categorical risk designation was appropriate because we have no historical information on OTPs (either from an enrollment, billing, or claims payment perspective) upon which we can fairly estimate the degree of risk they may pose.

Given the foregoing, we proposed:

- To state in new § 424.67(b)(3) that newly enrolled OTP providers would be screened at the high categorical risk level in accordance with the requirements of § 424.518(c).
- To add a new paragraph (iv) to § 424.518(c)(1) that would add newly enrolled OTPs to the types of providers and suppliers screened at the high categorical risk level.
- To add a new paragraph (xii) to § 424.518(b)(1) whereby OTPs that are revalidating their current Medicare enrollment (under § 424.515) would be screened at the moderate categorical risk level (which involves a site visit but does not include the fingerprint submission requirement of the high categorical risk level). This would be consistent with our approach towards several other provider and supplier types (for example, home health agencies) that are screened at the high categorical risk level when newly enrolling and at the moderate level when revalidating.
- Consistent with the addition of new § 424.518(b)(1)(xii), we proposed to require that, upon revalidation, the OTP must successfully complete the moderate categorical risk level screening required under § 424.518(b) in order to remain enrolled in Medicare. This provision would be designated as new § 424.67(d)(1)(iii).

(d) OTPs: Certification

Consistent with both section 1861(jjj)(2)(B) of the Act and § 8.11, we proposed in new § 424.67(b)(4)(i) that to enroll in Medicare, an OTP must have in effect a current, valid certification by SAMHSA for such a program. However, under § 424.67(b)(4)(ii), we proposed that we would not accept a provisional certification under § 8.11(e) in lieu of the certification described in § 8.11(a). We believed that the OTP certification requirement in section 1861(jjj)(2)(B) of the Act refers to full SAMHSA certification rather than provisional certification.

(e) OTPs: Managing Employees

Consistent with sections 1124 and 1124A of the Act, an enrolling provider or supplier must disclose all of its managing employees on the Form CMS–855 application. Thus, we proposed in new § 424.67(b)(5) that all OTP's staff who meet the regulatory definition of managing employee in § 424.502 must be reported on the Form CMS–855 application and/or any applicable supplement. Such individuals would include, but not be limited to, the OTP's medical director and program sponsor (both as described in § 8.2).

(f) Standards Specific to OTPs

In light of the previously mentioned concerns about the nationwide opioid crisis and the need for drugs to be prescribed and, moreover, dispensed, in a careful, reasonable manner, we also proposed certain enrollment standards unique to the services that OTPs provide.

In new § 424.67(b)(6)(i), we proposed that an OTP must not employ or contract with a prescribing or ordering physician or other eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted (as that term is defined in 42 CFR 1001.2) of a federal or state felony that we deem detrimental to the best interests of the Medicare program and its beneficiaries, based on the same categories of detrimental felonies, as well as case-by-case detrimental determinations, codified at § 424.535(a)(3). This provision would apply irrespective of whether the individual in question is: (1) Currently dispensing narcotics at or on behalf of the OTP; or (2) a W–2 employee of the OTP.

In new § 424.67(b)(6)(ii), we proposed that the OTP must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who is revoked from Medicare under § 424.535 or any other applicable section in Title 42, or who is on the preclusion list under § 422.222 or § 423.120(c)(6). *(See https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html* for background information on the preclusion list).

In § 424.67(b)(6)(iii), we proposed that the OTP must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who has a prior adverse action imposed by a state oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. We would consider the factors specified at § 424.535(a)(22) (discussed in more detail below) in each case of patient harm that potentially applies to this provision.

The overriding rationale for these provisions is our view that OTP personnel who have engaged in problematic behavior present a potential threat to the OTP's patients and to the Trust Funds.

(g) Provider Agreement

As previously mentioned, section 2005(d) of the SUPPORT Act amended section 1866(e) of the Act by adding a new paragraph (3) classifying OTPs as Medicare providers, though only with respect to the furnishing of opioid use disorder treatment services. Under section 1866(a)(1) of the Act, all Medicare providers (as that term is defined in section 1866(e) of the Act) must enter into a provider agreement with the Secretary. (Section 1866(a)(1) of the Act outlines required terms of the provider agreement, such as allowed charges for furnished services.)

Consistent with these requirements, we proposed two new provisions. In new § 424.67(b)(7)(i), we proposed that an OTP must, in accordance with the provisions of 42 CFR part 489, sign (and adhere to the terms of) a provider agreement with CMS in order to participate and enroll in Medicare. In new § 424.67(b)(7)(ii), we proposed that an OTP's appeals under part 498 of a Medicare revocation (under § 424.535) and of a termination of its provider agreement (under § 489.53) must be filed jointly and, as applicable, considered jointly by CMS under part 498.

Regarding this latter provision, we believe that having dual, separate appeals processes for OTPs would impose unnecessary administrative burdens on OTPs and CMS. A single appeals process would, in our view, be more efficient. We did, however, solicit comment on this proposed consolidated appeals process, including suggestions of alternative processes and the

potential operational components thereof.

(h) OTPs: Other Applicable Requirements

To ensure that the OTP meets all other applicable requirements for enrollment, we proposed at § 424.67(b)(8) that the OTP must comply with all other applicable enrollment requirements specified in § 424.67 and in part 424, subpart P.

(i) OTPs: Denial of Enrollment and Appeals Thereof

We proposed to state in new § 424.67(c) that CMS may deny an OTP's enrollment application on either of the following grounds:

- The provider does not have in effect a current, valid certification by SAMHSA as required under § 424.67(b)(4) or fails to meet any other applicable requirement in § 424.67.
- Any of the reasons for denial of a prospective provider's or supplier's enrollment application in § 424.530 applies.

We also proposed that an OTP may appeal the denial of its enrollment application under part 498.

The purposes of these provisions were to, respectively, ensure: (1) The OTP's compliance with § 424.67 and all other applicable enrollment requirements; and (2) that the OTP has the same appeal rights as all other provider and supplier types.

(j) OTPs: Continued Compliance, Standards, and Reasons for Revocation

For reasons identical to those behind our addition of § 424.67(c), we proposed several provisions in new § 424.67(d).

In paragraph (d)(1), we proposed to state that, upon and after enrollment, an OTP:

- Must remain validly certified by SAMHSA as required under § 8.11.
- Remains subject to, and must remain in full compliance with, the provisions of part 424, subpart P, as well as those in § 424.67. This includes, but is not limited to, the provisions of § 424.67(b)(6), the revalidation provisions in § 424.515, and the deactivation and reactivation provisions in § 424.540.

In paragraph (d)(2), we proposed that CMS may revoke an OTP's enrollment if:

- The provider does not have a current, valid certification by SAMHSA or fails to meet any other applicable requirement or standard in § 424.67, including, but not limited to, the OTP standards in §§ 424.67(b)(6) and (d)(1).
- Any of the revocation reasons in § 424.535 applies.

Finally, in new paragraph (d)(3), we proposed that an OTP may appeal the revocation of its enrollment under part 498.

(k) OTPs: Prescribing Individuals

In new § 424.67(e)(1) (and with respect to payment to OTP providers for furnished drugs), we proposed that the prescribing or medication ordering physician's or other eligible professional's National Provider Identifier must be listed on Field 17 (the ordering/referring/other field) of the Form CMS–1500 (Health Insurance Claim Form; 0938–1197) (or the digital equivalent thereof)). We believed that this requirement would help us: (1) Ensure that the physician or other eligible professional in question is qualified to prescribe drugs on behalf of the OTP; and (2) monitor the prescribing individual in relation to each claim. This requirement would have to be met in order for an OTP claim for a prescribed drug to be paid. To avoid the impression, however, that this is the only requirement necessary for claim payment, we proposed to further clarify in new paragraph (e)(2) that all other applicable requirements in § 424.67, part 424, and part 8 must also be met.

(l) OTPs: Relationship to 42 CFR Part 8

To help ensure that OTPs understand their continuing need to comply with the provisions in Part 8 (several of which are referenced above) and to clarify that the provisions in § 424.67 are generally restricted to the enrollment process, we proposed to state in new § 424.67(f) that § 424.67 shall not be construed as: (1) Supplanting any of the provisions in part 8; or (2) eliminating an OTP's obligation to maintain compliance with all applicable provisions in part 8.

(m) Effective and Retrospective Date of OTP Billing Privileges

Section 424.520 outlines the effective date of billing privileges for provider and supplier types that are eligible to enroll in Medicare. Paragraph (d) thereof sets forth the applicable effective date for physicians, NPPs, physician and NPP organizations, and ambulance suppliers. This effective date is the later of: (1) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the supplier first began furnishing services at a new practice location. Similarly, § 424.521(a) states that physicians, NPPs, physician and NPP organizations, and ambulance suppliers may retrospectively bill for services when the supplier has met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to:

- 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Pub. L. 100–707, enacted November 23, 1988), 42 U.S.C. 5121–5206 (Stafford Act), precluded enrollment in advance of providing services to Medicare beneficiaries.

To clarify the effective date of billing privileges for OTPs and to account for circumstances that could prevent an OTP's enrollment prior to the furnishing of Medicare services, we proposed to include newly enrolling OTPs within the scope of §§ 424.520(d) and 424.521(a).

We also sought public feedback on additional means of preventing fraud, waste, and abuse in OTP settings; for instance, we noted that we would appreciate suggestions—based on stakeholder experience in the OUD and OTP arenas—from which we could develop further regulatory authority to take action against problematic OTPs.

(3) Summary of the Public Comments on OTP Enrollment Provisions and the CMS Responses

We received comments concerning our proposed OTP enrollment provisions from approximately 15 stakeholders. The comments are summarized below, followed respectively by our responses thereto.

Comment: Several commenters stated that our proposed assignment of newly enrolling OTPs to the high categorical risk level was reasonably prudent due to our: (1) Stated lack of historical information on OTPs; and (2) safety concerns. One commenter added that CMS might wish to reconsider this risk level assignment once sufficient experience with the OTP enrollment process has been attained.

Response: We appreciate the commenters' support. While we cannot commit to any future risk level reclassification for initially enrolling OTPs, we will closely monitor OTP enrollment over the coming years and, if warranted, consider potential regulatory revisions that serve the best interests of the Medicare program and its beneficiaries.

Comment: One commenter stated that there could be heightened risk in OTP facilities compared to other settings, for the services provided involve the

prescribing and dispensing of controlled substances and a complex subset of patients dealing with addiction. However, the commenter cautioned CMS against overly restrictive policies that may hinder patient care or physician practices. Another commenter encouraged CMS to streamline and minimize the cost associated with the OTP enrollment process.

Response: In establishing our OTP enrollment proposals, we strived to protect the Medicare program, the Trust Funds, and beneficiaries while (1) avoiding the imposition of unnecessary and excessively burdensome and costly requirements and (2) ensuring patient access to care as much as possible; that is, our aim was to propose requirements consistent with program and patient safety without needlessly burdening OTPs. We believe this approach will prove successful in appropriately balancing the needs addressed by the commenters.

Comment: Several commenters expressed support for the proposed assignment of enrolled OTPs to the moderate level of categorical screening and the proposed changes to §§ 424.520 and 424.521 regarding retroactive billing.

Response: We appreciate the commenters' support.

Comment: One commenter that is currently enrolling their locations under the ''Clinic/Group Practice'' category on the Form CMS–855B questioned whether CMS will be creating a new ''OTP Provider'' category on the form. If so, the commenter asked whether clinics that currently have a Medicare number will have to re-enroll as an OTP.

Response: We are in the process of revising the Form CMS–855B as part of this rule to include a new category for OTPs. Since OTPs are a provider type that is distinct from clinics/group practices, with different requirements and conditions for enrollment, a currently enrolled clinic/group practice will need to separately enroll as an OTP if it wishes to bill for OTP services.

Comment: Several commenters stated that a provisional certification should be sufficient to satisfy the certification requirement at proposed § 424.67(b)(4), at least for the 12-month period before full certification is granted. The commenters stated that: (1) This would expand access to OTP care; (2) provisional certification is indeed a type of SAMHSA certification that has been used for many years to enable new OTPs to treat patients temporarily; and (3) failure to accept provisional certification represents a barrier to treatment that is inconsistent with congressional intent.

Response: As mentioned previously, section 1861(jjj)(2)(B) of the Act states that an OTP must have in effect a certification by SAMHSA. We interpret this requirement to mean full SAMHSA certification rather than provisional certification because the statute does not specify that provisional certification is acceptable in lieu of full certification. We also note that provisional certification under § 8.11(e) applies to OTPs that do not have a current SAMHSA certification but have applied for accreditation with an accreditation organization. Yet section 1861(jjj)(2)(C) of the Act requires actual accreditation rather than the mere application for accreditation. Therefore, since the latter cannot be accepted for enrollment purposes, we do not believe a provisional certification (which, again, pertains to non-accredited parties) can, either.

Comment: One commenter questioned whether an organization with multiple programs and clinics will be able to apply (via the Form CMS–855B) for a single provider number and bill for services furnished by each program under this number.

Response: Separately certified and accredited OTPs must be separately enrolled. Multiple OTPs cannot be grouped under a single enrollment.

Comment: Several commenters requested verification that OTP enrollment will be done at the provider level under the program's NPI and will not require the enrollment or credentialing of physicians and practitioners employed by the OTP. The commenters stated that if the latter were required: (1) It could pose a significant burden on OTPs; and (2) practitioners who could not become enrolled would lose their employment with the OTP, which could hinder the OTP's ability to furnish care. The commenters also requested clarification as to how such a requirement would impact other practices and settings where the physician or practitioner may work.

Response: The OTP facility itself will be enrolled. The physicians and practitioners will not have to enroll as part of the OTP's enrollment.

Comment: Several comments sought clarification regarding: (1) Whether there is a specific timeframe in which OTPs will have to enroll; and (2) when OTPs can begin submitting applications for enrollment.

Response: OTPs may submit applications immediately, and we encourage them to do so to begin billing on and after the OTP benefit commencement date of January 1, 2020.

Comment: Several commenters stated that SAMHSA's existing certification and accreditation requirements are sufficient to ensure an OTP's quality of service and that no additional conditions for Medicare enrollment should be required. As evidence of such, the commenters cited a statement in the proposed rule that the certification and accreditation requirements are ''sufficient to ensure the health and safety of individuals being furnished services by OTPs, as well as the effective and efficient furnishing of such services.'' Accordingly, the commenters stated that no requirements beyond certification and accreditation should be necessary, especially given that OTPs are already heavily regulated.

Response: We disagree with the commenters. The statement cited by the commenters was never meant to imply that OTP enrollment would or should consist merely of the submission of a copy of the OTP's SAMHSA certification and accreditation, without any need for completion of the Form CMS–855B and CMS' verification of the information thereon. As already mentioned, section 1861(jjj)(2)(A) of the Act requires that an OTP be enrolled in Medicare under section 1866(j) of the Act; moreover, section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. Consistent with (and even prior to) section 1866(j) of the Act, we established a thorough enrollment process designed to ensure that all providers and suppliers meet Medicare requirements. We believe the commenters are, in effect, asking for an exemption from this process for OTPs. CMS cannot consent to this. All providers and suppliers are required to adhere to our enrollment requirements, which have been longstanding, and there is nothing in section 1861(jjj)(2)(A) of the Act to indicate that OTPs were meant to be exempt. We further note that the SAMHSA certification and accreditation processes, while extremely crucial safeguards, do not involve reviews of whether the OTP meets Medicare requirements. However, our existing enrollment process does, which is why the latter is needed.

Comment: Several commenters opposed our assignment of OTPs to the high-risk screening level on several grounds. The commenters stated that CMS should already have sufficient data from state Medicaid agencies regarding OTP risk, meaning that our contention that we lack historical information concerning OTPs is without merit. Commenters also stated that OTPs are

already subject to significant regulation and oversight at the federal, state, and even local levels. Adding another level of supervision via high-risk screening would, they stated, be costly, redundant, and unnecessarily burdensome for OTPs, so much so that it could delay the enrollment of OTPs and thus deny prompt care to patients. The commenters also asserted that a high-risk screening designation creates an unwarranted stigma about OTPs and methadone treatment without factual support.

Response: Notwithstanding the commenters' statements concerning Medicaid, we do not have any historical information on OTPs in the context of Medicare participation. Medicaid and Medicare are two distinct programs with differing requirements. As such, and given the type of services performed at OTPs in light of the opioid epidemic, we believe that a robust scrutiny of newly enrolling OTPs is important. Indeed, we believe that it is important for all newly-recognized Medicare provider and types (due to Medicare's general lack of history associated with them) to be closely reviewed. Nevertheless, we appreciate and understand the commenters' concerns, and we recognize that many SAMHSA-certified OTPs have been in operation well before the enactment of the SUPPORT Act on October 24, 2018. Consequently, we are revising our proposed provisions such that newly enrolling OTPs that have been fully and continuously certified by SAMHSA since October 23, 2018, will be assigned to the moderate risk level of categorical screening. Those that have not been fully and continuously certified by SAMHSA since that date will be subject to the originally proposed high-risk level of categorical screening. (All revalidating OTPs will remain at the moderate level as proposed.)

We believe this approach will help balance the need to reduce the overall burden on the OTP community with the importance of ensuring that newer, more recently established OTPs (that, perhaps, have a shorter history of sustained performance) are appropriately screened. We also emphasize that neither our proposed nor our final risk categories were or are meant to stigmatize the OTP community. Rather, our objective is to ensure that OTPs, like all Medicare-enrolling providers and suppliers, are appropriately screened.

Comment: Several commenters stated that the requirement that OTPs not employ or contract with professionals convicted of a felony within the last 10 years or with a prior adverse action with the state oversight board is discriminatory. The commenters stated that many individuals working in substance use disorder treatment entered the field because they themselves are in recovery. Commenters stated that individuals should not be discriminated against: (1) For crimes they may have committed while still in an active disease state; or (2) if they have satisfactorily met requirements of the state's recovering professionals program.

Response: We respectfully disagree that this requirement is discriminatory, and it was in no manner intended to be. Our sole concern was to safeguard the Medicare program and its beneficiaries from individuals who could present a threat. We further note that there is precedent for the requirement in question. Under §§ 424.530(a)(3) and 424.535(a)(3), CMS may deny or revoke enrollment if the provider, supplier, or any *owner* or *managing employee* of the provider or supplier was, within the preceding 10 years, convicted of a federal or state felony that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. A similar provision at § 424.205(e)(1)(v) exists for the Medicare Diabetes Prevention Program (MDPP) coaches, who are prohibited from furnishing MDPP services if they have been convicted (within the previous 10 years) of one of the federal or state felonies outlined in that provision. Given this, and, more importantly, the very sensitive nature of controlled substances and medication-assisted treatment, we believe that the OTP employment provision in question is appropriate and necessary.

Nonetheless, we stress that this is a discretionary provision, in the sense that the felony in question must be one that CMS determines to be detrimental to the best interests of the Medicare program and its beneficiaries based on our review of the factors in § 424.535(a)(3). We understand the commenters' concerns, and it should not be assumed that every felony conviction and the circumstances surrounding it will meet the standard described in the previous sentence.

Comment: Several commenters stated that our reference in the proposed rule to patient brokers and excessive stays in sober homes represents a poor and possibly discriminatory illustration of an OTP's risk potential.

Response: The statement that the commenter cited was not intended to denigrate OTPs. It was merely an example we have seen of disconcerting provider behavior in the context of drug treatment.

Comment: Regarding the proposed list of prescribing, ordering, or dispensing physicians and other eligible professionals, one commenter stated that the term ''eligible professional'' (as defined in section 1848(k)(3)(B) of the Act) does not include pharmacists. The commenter stated that some pharmacists may be legally authorized to prescribe, order, or dispense medications. Thus, limiting the list to physicians and other eligible professionals could imply that pharmacists cannot perform these functions. The commenter recommended that CMS modify this requirement to include pharmacists within the category of individuals who should be reported on the aforementioned list.

Response: We agree and will revise § 424.67(b)(1)(i) to include pharmacists within the scope of the list requirement, though this should not be construed as implying that a pharmacist qualifies as an eligible professional under section 1848(k)(3)(B) of the Act.

Comment: One commenter questioned whether per diem nursing staff (such as registered nurses) will need to be listed on the Form CMS–855B OTP supplement.

Response: As the previous commenter noted and as indicated in our response, the individuals listed under § 424.67(b)(1)(i) are physicians, other eligible professionals, and pharmacists. Individuals, such as registered nurses, who do not fall within these categories need not be listed. (The definition of ''eligible professionals'' in section 1848(k)(3)(B) of the Act, though, does include practitioners described in section 1842(b)(18)(C) of the Act, and the definition of ''practitioners'' includes nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists, among other individuals.) However, we note that individuals to whom § 424.67(b)(1)(i) applies can be either employees or contracted personnel so long as they are legally authorized to prescribe, order, or dispense controlled substances on the OTP's behalf. We believe ''per diem'' staff fall within the classification of contracted personnel, for while they are not employees, they are acting on behalf of the OTP per a contractual arrangement. Therefore, they would have to be listed. We will revise the regulatory text of § 424.67(b)(1)(i) to clarify that the individual need not be a W–2 employee of the OTP.

Comment: One commenter requested clarification regarding whether physicians or other eligible professionals participating in

continuous improvement activities (such as a quality assessment or peer review) without a state or federal government action against them would be denied participation in an OTP or other Medicare program.

Response: Engagement in the continuous improvement activities the commenter describes does not, in and of itself: (1) Constitute grounds for denial or revocation of Medicare enrollment; or (2) invoke the prohibitions in § 424.67(b)(6).

(4) Final OTP Enrollment Provisions

After considering the comments received, we are finalizing our provisions as proposed with several exceptions.

Section 424.67(b)(1)(i) is expanded to apply to all physicians, other eligible professionals, and pharmacists who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP (regardless of whether the individual is a W–2 employee of the OTP).

In § 424.67(b)(3), we are revising this paragraph to state that applicants must successfully complete the assigned categorical risk level screening required under, as applicable, § 424.518(b) and (c). This is intended to accommodate the two aforementioned levels of screening for newly enrolling OTPs.

Proposed § 424.518(b)(1)(xii), which stated that revalidating OTPs would be subject to the moderate risk level of categorical screening, will be re-designated as new § 424.518(b)(1)(xiii). Consistent with our prior discussion on this issue, prospective OTPs that have been fully and continuously certified by SAMHSA since October 23, 2018 will be included in revised § 424.518(b)(1)(xii).

In § 424.518(c)(1)(iv), which outlines providers and suppliers in the high-risk level of categorical screening, we are revising this provision to include prospective (newly enrolling) OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018.

We did not receive requested public feedback on additional means of preventing OTP fraud, waste, and abuse from which we could consider future regulatory action. However, we always welcome such suggestions.

2. Revision and Addition to Denial and Revocation Reasons in §§ 424.530 and 424.535

a. Improper Prescribing

Under existing § 424.535(a)(14), CMS may revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part D drugs that:

- Is abusive and/or represents a threat to the health and safety of Medicare beneficiaries; or
- Fails to meet Medicare requirements.

This revocation reason is designed to address situations where prescribers of Part D drugs engaged in prescribing activities that were or could be harmful to Medicare beneficiaries and the Trust Funds or were otherwise inconsistent with Medicare policies. Since the provision's inception, we have revoked the enrollments of physicians and practitioners who have engaged in a variety of improper prescribing practices. However, given the nationwide opioid epidemic, we remain concerned about such behavior. Therefore, we proposed that § 424.535(a)(14) should no longer be restricted to Part D drugs but must extend to all Medicare drugs, including Part B drugs; specifically, the term ''Part D drugs'' in the opening paragraph of § 424.535(a)(14) would be changed to ''Part B or D drugs.'' We noted that this proposal would affect prescriptions of any Part B or D drugs, not merely those prescriptions given to beneficiaries using OTPs.

b. Patient Harm

As referenced previously, and due to the importance of ensuring patient safety in all provider and supplier settings (not merely those involving OTPs), we also proposed to add § 424.535(a)(22) as a new revocation reason; this would be coupled with a concomitant new denial reason in § 424.530(a)(15). These two paragraphs would permit us to revoke or deny, as applicable, a physician's or other eligible professional's (as that term is defined in section 1848(k)(3)(B) of the Act) enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation or denial on this ground is appropriate, CMS would consider the following factors:

- The nature of the patient harm.
- The nature of the physician's or other eligible professional's conduct.
- The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

++ License restriction(s) pertaining to certain procedures or practices,

++ Required compliance appearances before state oversight board members,

++ Required participation in rehabilitation or mental/behavioral health programs,

++ Required abstinence from drugs or alcohol and random drug testing,

++ License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge),

++ Administrative/monetary penalties, or

++ Formal reprimand(s).

- If applicable, the nature of the IRO determination(s).
- The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.
- Any other information that CMS deems relevant to its determination.

As noted in the proposed rule and in previous rulemaking efforts, we remain concerned about instances of physician or other eligible professional misconduct, and we believe our authority under sections 1102, 1866(j)(1)(A), and 1871 of the Act to take action to stem such behavior should be expanded to include the scenarios identified in § 424.530(a)(15) and § 424.535(a)(22). State oversight boards, such as medical boards and other administrative bodies, have found certain physicians and other eligible professionals to have engaged in professional misconduct and/or negligent or abusive behavior involving patient harm. In addition, IRO determinations have offered valuable, independent analyses and findings of provider misconduct that we should have the opportunity to use to promote the best interests of Medicare beneficiaries. We outlined our belief that our proposed revocation and denial authorities would improve overall patient care by preventing certain problematic physicians and other eligible professionals from treating Medicare patients.

We stated in the proposed rule that §§ 424.530(a)(15) and 424.535(a)(22) would apply to physicians and other eligible professionals in OTP and non-OTP settings. In addition, to clarify the scope of the term ''state oversight board'' in the context of §§ 424.530(a)(15) and 424.535(a)(22), we

proposed to define this term in § 424.502. Specifically, we proposed (for purposes of §§ 424.530(a)(15) and 424.535(a)(22) only) to define ''state oversight board'' to mean any state administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the state.

We solicited comment not only on our definition of ''state oversight board'' but also on our proposed revocation and denial authorities.

c. Summary of the Public Comments on Improper Prescribing and Patient Harm and the CMS Responses

We received comments concerning our improper prescribing and patient harm provisions from approximately 30 stakeholders. The comments are summarized below, followed by our responses.

Comment: Several commenters opposed not only our proposed revision of § 424.535(a)(14) but also the existing version of (a)(14). The commenters expressed concern that some types of prescribers and specialties would be unfairly targeted and prevented from legitimate prescribing. The commenters added that what may be considered excessive prescribing for the general population could be clinically appropriate given a patient's individual circumstances and conditions (particularly in pain management and palliative care). Other commenters stated that while it is important to monitor highly egregious prescribers, CMS must ensure that physicians who are prescribing appropriately, even at higher doses (beyond certain guidelines or recommended thresholds), are not unnecessarily sanctioned or disciplined. Erroneous sanctions, they claimed, could have negative impacts on patient care, deny access to new and innovate forms of treatment, and spur clinicians to restrict their prescribing practices based on potential revocation concerns.

Response: Since the commencement of our enforcement of existing § 424.535(a)(14), we have not targeted particular physician or practitioner specialties and have been extremely careful in our application of the criteria outlined in this provision. The commenters are correct that certain situations could warrant different levels of prescribing, and the flexibility afforded by the factors in § 424.535(a)(14) has allowed us to thoroughly consider and address such differing scenarios. We stress that this will not change with our expansion of § 424.535(a)(14) to include Part B drugs.

We have received no indication that the application of § 424.535(a)(14) has generally caused physicians and other eligible professionals to significantly reduce their levels of prescribing or caused barriers to Part D drugs. Given this, we do not foresee such problems with the addition of Part B drugs.

Comment: Several commenters stated that § 424.535(a)(14) duplicates current safety mechanisms and revocation reasons, overly burdens prescribers, and effectively represents CMS engaging in second-guessing the clinical determinations of medical professionals.

Response: We respectfully disagree. We currently have no revocation authority other than § 424.535(a)(14) to directly address abusive prescribing practices. In addition, we have applied § 424.535(a)(14) very sparingly and only in demonstrably egregious instances of improper prescribing. Therefore, the only persons who have been burdened are the extremely few who have engaged in such practices, while the overwhelming preponderance of the remaining 2 million Part D prescribers have been unaffected. Also, the fact that only severe cases have triggered § 424.535(a)(14) indicates that CMS gives great deference to the prescribing decisions of the provider community as a whole.

Comment: Many commenters opposed our additions of §§ 424.530(a)(15) and 424.535(a)(22) and urged us to withdraw them. Commenters stated that these provisions are overly vague, do not furnish sufficient guidance to physicians and other eligible professionals as to what the expectations are, and create excessive uncertainty and burden for these individuals. Commenters also stated that § 424.535(a)(22) would unfairly impose harsh and disproportionate sanctions on providers for potentially minor violations. Another commenter expressed particular concern about young and inexperienced physicians who could be punished by CMS for modest transgressions. Additional commenters stated that a Medicare revocation under § 424.535(a)(22) would trigger an automatic Medicaid enrollment termination as well as termination from private payer programs, which could devastate the individual's medical practice.

Commenters further stated that § 424.535(a)(22) would negatively affect Medicare beneficiaries' access to health services because: (1) A revoked provider's patients would have to seek care elsewhere; and (2) the number of available physicians and other eligible professionals (including, perhaps, the group practices with which they are affiliated) will be unnecessarily reduced, leading to provider shortages. Commenters added that this could be especially problematic in remote and underserved areas and with specialized services. They stated that the patient harm that CMS seeks to deter could actually increase through a restriction of available care.

Response: While we appreciate these comments, we reiterate that the only actions under §§ 424.530(a)(15) and 424.535(a)(22) that could lead to a denial or revocation are those resulting in patient harm. We believe that some commenters assumed that the action itself, regardless of any impact on a patient, would be sufficient for CMS to invoke these provisions. This is incorrect. Patient harm must be a result. Since many determinations by state oversight boards and similar bodies do not involve patient harm, the physicians or other eligible professionals to which such determinations pertain will not be affected by §§ 424.530(a)(15) and 424.535(a)(22) in any way.

Concerning the first set of comments summarized here, we do not believe that §§ 424.530(a)(15) and 424.535(a)(22) are overly vague or lack sufficient guidance. We outline in detail both the types of sanctions or actions that could invoke these provisions as well as the criteria that we will consider in our determinations. Although §§ 424.530(a)(15) and 424.535(a)(22), like several of our other denial and revocation reasons, might appear to some to be more open-ended and less clear-cut than, for example, a revocation based on the provider's exclusion from Medicare by the Office of Inspector General (OIG)(see § 424.535(a)(2)), this is because of our need for flexibility in addressing various patient harm situations. We believe that §§ 424.530(a)(15) and 424.535(a)(22) appropriately balance (1) the need for clarity concerning the actions that these provisions cover with (2) the importance of having sufficiently extensive criteria to ensure a fair and exhaustive review of the case. With respect to burden, the only physicians and other eligible professionals (out of a Medicare-enrolled or potentially enrolled universe of well over 2 million) who could be impacted by these provisions are those very few who engage in the abusive behavior outlined therein. All other physicians and other eligible professionals will not be burdened.

Regarding the second group of comments, we reiterate that the action must first have resulted in patient harm before CMS will even consider reviewing the case; without patient

harm, the matter is moot from the standpoint of §§ 424.530(a)(15) and 424.535(a)(22). We are also very cognizant of the relative severity of a Medicare revocation and the impact it can have on a physician's or other eligible professional's career, which is why we have historically exercised our authority under § 424.535(a)'s revocation provisions only when the affected party's behavior is such that a revocation (after our thorough review of the case) is genuinely warranted. We intend to apply this principle to situations involving § 424.535(a)(22). Moreover, and of paramount importance, we intend to invoke § 424.535(a)(22) strictly in cases where the behavior in question (such as, but not limited to, sexual misconduct) and the consequent patient harm was significant in nature.

Finally, we do not believe that § 424.535(a)(22) will impair patient access to health care, specialized or otherwise. We have received few reports of access to care issues resulting from previous revocation action on our part under § 424.535(a). Considering, as stated previously, that only a very small number of physicians and other eligible professionals would be affected by § 424.535(a)(22), we do not foresee the latter provision creating barriers to care. Nonetheless, should such issues unexpectedly arise after § 424.535(a)(22)'s implementation, we will, as needed, consider mechanisms for resolving them.

Comment: Several commenters stated that § 424.535(a)(22) would discourage physicians and other eligible professionals from self-reporting to medical boards, for they will be reluctant to disclose behavior (such as drug use and alcoholism) that could result in IRO or state action leading to a Medicare revocation. This, the commenters stated, makes the patient harm provision inconsistent with the nationwide effort to reduce the stigma associated with seeking treatment for substance abuse. The commenters added that § 424.535(a)(22) could also have a negative effect on medical boards' willingness to discipline individuals (or could otherwise affect their decisions) because doing so could invoke § 424.535(a)(22). While remaining opposed to the provision, the commenters urged CMS to, at a minimum, narrow its scope to avoid targeting individuals engaged in mental/behavioral health and/or substance use disorder treatment and monitoring with their state physician health programs.

Response: We appreciate and understand the commenters' concerns. We do not wish to discourage physicians and other eligible professionals from seeking whatever help they may need. Accordingly, we will remove the following criteria from §§ 424.530(a)(15) and 424.535(a)(22):

- Required participation in rehabilitation or mental/behavioral health programs.
- Required abstinence from drugs or alcohol and random drug testing.

We will also add a new paragraph to §§ 424.530(a)(15) and 424.535(a)(22) that specifically excludes these actions from the provisions' purviews. However, we note that the action or order must be restricted to required participation in a rehabilitation or mental/behavioral health program or abstinence from drugs or alcohol and random drug testing. If the action involves either of these directives as well as an additional sanction that involves patient harm, the latter (but not the rehabilitation, abstinence, or testing portion of the directive) could invoke § 424.530(a)(15) or § 424.535(a)(22).

To illustrate how this change would apply, consider the following examples:

Example 1— In a case involving patient harm, a state oversight board requires Dr. X to enter a rehabilitation program. There are no other sanctions in the state's order. Since the state's action is restricted exclusively to rehabilitation, § 424.530(a)(15) or § 424.535(a)(22) would not apply.

Example 2— In a case not involving patient harm, a state oversight board issues a decision pertaining to Dr. X that: (1) Requires him to enter a rehabilitation program; and (2) imposes a fine on him. Sections 424.530(a)(15) and 424.535(a)(22) would not apply in any event because no patient harm was present.

Example 3— In a case involving patient harm, a state oversight board issues a decision pertaining to Dr. X that: (1) Requires him to enter a rehabilitation program; and (2) restricts his license for a 60-day period due to sexual misconduct. CMS would consider the board decision under §§ 424.530(a)(15) and 424.535(a)(22), as applicable, because of the license restriction based on sexual misconduct.

This change, in our view, will help reassure physicians and other eligible professionals that they can seek the assistance they require without concern that their rehabilitation and treatment efforts would be penalized under §§ 424.530(a)(15) and 424.535(a)(22). It will balance this very important need with our belief that other actions within the state oversight board's directive could warrant consideration under §§ 424.530(a)(15) and 424.535(a)(22).

Comment: Numerous commenters stated that the patient harm provisions fail to focus on identifying and addressing demonstrably problematic providers and suppliers. For this reason alone, the commenters stated that: (1) The provisions should be withdrawn; and (2) CMS should instead adopt other means of identifying and disciplining such parties. If CMS decides to finalize §§ 424.530(a)(15) and 424.535(a)(22), the commenters urged CMS to take a much more targeted approach by, for instance, restricting the provisions to physicians and other eligible professionals who are identified as outliers (or otherwise higher-risk) through data analytics.

Response: We believe that our previously mentioned restriction of §§ 424.530(a)(15) and 424.535(a)(22) to egregious behavior are consistent with the commenters' recommendation to focus on outlier behavior. The overwhelming preponderance of physicians and other eligible professionals have not had a serious (nor, for that matter, any) state oversight board action. Those who have, we believe, could be considered outliers in terms of the volume and degree of professional misconduct.

Comment: Several commenters requested that CMS furnish evidence showing a correlation between disciplinary actions taken (or not taken) by state oversight boards and fraud, abuse, and/or beneficiary harm in the Medicare program.

Response: It has been our experience throughout the years that instances of problematic Medicare provider behavior detected at the state or federal level can pose, and have posed, threats to the Medicare program, the Trust Funds, and beneficiaries. Indeed, we have come across a number of such cases. In one situation, for example, a physician was placed on probation, fined, and suspended by the state board after multiple accusations by his patients for sexual assault. However, he was permitted to maintain his medical license, during which period he continued to sexually assault additional patients. It was not until multiple years after the initial fine and probation period that the state finally revoked his medical license, and it was only after this license action that CMS was able to revoke the physician's Medicare enrollment. However, with our new patient harm provisions, CMS could have taken immediate action based on the initial probation, fine, and suspension, thus perhaps avoiding the subsequent patient abuse that occurred.

Comment: Several commenters stated that CMS did not articulate clear standards for how it will determine (based on its assessment of the proposed factors) whether there are sufficient grounds to invoke §§ 424.530(a)(15) and 424.535(a)(22). The commenters added that the factor in each provision

concerning CMS' consideration of other relevant information gives CMS overly broad authority in making enrollment decisions.

Response: We disagree that these provisions lack standards indicating how CMS will review cases thereunder. We clearly outline the criteria we will consider in our determinations. If the commenter is suggesting that each factor should contain definitive benchmarks, such as a minimum number of patients who were harmed by the conduct in question, we respectfully do not concur. As we have stated and several commenters have noted, every situation is different. We must have the discretion to fairly and fully consider the specific facts and circumstances involved. To establish firm thresholds could allow an individual who is repeatedly engaging in abusive behavior to avoid a denial or revocation because (using our previous example) he or she did not harm a certain number of patients. Such a result would be inconsistent with our obligation to protect the Medicare program and its beneficiaries.

Nonetheless, we recognize the commenters' concerns regarding the factor involving our consideration of any other information we deem relevant. To provide greater clarity to affected physicians and other eligible professionals concerning the bases of our §§ 424.530(a)(15) and 424.535(a)(22) determinations, we will remove this factor from both provisions. However, we emphasize that this will not affect our continued inclusion of this same factor in several of our existing denial and revocation reasons. Nor are we precluding its use in possible future provisions. It is only due to the unique circumstances and potential fact patterns associated with our patient harm provisions that the criterion in question is being removed.

Comment: One commenter stated that a physician or other eligible professional, as well as his co-workers and fellow providers, might prove reluctant to report his or her medical errors due to fear of a possible enrollment revocation. This commenter stated that this makes the entire health system less safe for Medicare beneficiaries.

Response: We understand the commenter's concern. However, we believe that our restriction of §§ 424.530(a)(15) and 424.535(a)(22) to significant cases of patient harm will avoid the situation the commenter contemplates.

Comment: Several commenters expressed concern that CMS did not formally define or clarify the meaning and scope of the term ''patient harm.'' The commenters stated that it would be inappropriate for CMS to deny or revoke enrollment without the provider understanding CMS' interpretation of the term. They urged CMS to be much more specific on what would qualify as patient harm and to explain how it would make patient harm determinations.

Response: Concerning the commenters' second request, we previously indicated that in making determinations under the patient harm provisions, we will consider all of the specified factors as well as the totality of the circumstances. This will include a close and thorough analysis of the nature and degree of the patient harm. As for formally and officially defining the latter term in regulation, we believe the meaning of the term ''patient harm is self-evident, in that it involves some form of physical and/or psychological injury to the patient.

Comment: Several commenters stated that patient harm and certain types of sanctions could occur through no fault of the provider and/or via an innocent error. Commenters cited instances where misleading or erroneous complaints were from irate or dissatisfied patients and their families or caregivers. To illustrate, an individual might: (1) Disagree with his physician's medically appropriate decision not to prescribe a certain medication; or (2) misunderstand the relative risks and benefits of a treatment as correctly communicated by the physician. The commenters stated that, in proposing its patient harm provisions, CMS overlooked the potential for such situations and the devastating consequences for innocent medical practitioners. One commenter stated that a better barometer of misconduct would be an intent to cause harm.

Response: We recognize the potential for erroneous or unfounded complaints. We believe that many of these will be detected as such and appropriately dismissed at the state oversight board level, in which case §§ 424.530(a)(15) and 424.535(a)(22) would not apply. As for restricting these provisions to instances of intentional patient harm, we disagree. Our overriding concern is with the harm itself, irrespective of whether it stemmed from the provider's willful misconduct, negligence, or other state of mind.

Comment: Several commenters cited our statement in the proposed rule that modest sanctions would not automatically result in a revocation. They stated that the regulatory text does not include this language but only lists the factors that CMS would consider in its determinations. The commenters stated that an informal preamble statement does not furnish sufficient certainty to providers and creates the potential for arbitrary CMS decisions. The commenters also stated that this preamble language should be codified in the regulatory text. Additional commenters stated that CMS should define or more thoroughly identify what constitutes a modest sanction.

Response: The language to which the commenters refer was simply background information designed to reassure stakeholders that not every case will result in a revocation. Such informal statements are typically not suitable for (and not included in) regulatory text and are more appropriately contained in the preamble. Furthermore, our discussions throughout this final rule should make clear that § 424.535(a)(22) will be applied: (1) With great care and circumspection; (2) in a non-arbitrary manner; (3) infrequently; and (4) only when the conduct and resulting patient harm were significant in nature.

We respectfully decline to formally define or specify what constitutes a modest sanction versus, for instance, a non-modest sanction. The types of possible state oversight board orders and sanctions are many and varied. To identify them and then classify each one as either modest or not would, we believe, give an erroneous impression that certain groups of sanctions related to patient harm would always, would never, or only sometimes result in specific CMS decisions. All cases and actions are different, and, as already stated, we must preserve our flexibility in considering each of them on their own facts and merits.

Comment: Several commenters stated that the list of sanctions that could trigger §§ 424.530(a)(15) and 424.535(a)(22) (for example, license restrictions) are not necessarily indicative of patient harm.

Response: We agree with these commenters, which is why we again reiterate that only those actions involving serious misconduct and patient harm could invoke §§ 424.530(a)(15) and 424.535(a)(22).

Comment: Several commenters stated that CMS does not have the statutory authority for §§ 424.530(a)(15) and 424.535(a)(22). They noted that CMS relies in part on sections 1102 and 1871 of the Act as authority for these new provisions. (Sections 1102 and 1871 of the Act furnish general authority for our establishment of these requirements, which are designed for the efficient administration of the Medicare program.) The commenters stated that

§§ 424.530(a)(15) and 424.535(a)(22) are not necessary to efficiently run the Medicare program; rather, by potentially interrupting care to Medicare beneficiaries, these provisions could lead to a more inefficient Medicare program. Second, the commenters noted that section 1866(j)(1)(A) of the Act requires the Secretary to establish an enrollment process for providers and suppliers. The commenters stated that this statute lists several components (for example, the establishment of temporary enrollment moratoria) that must be part of this process. None of these, however, include the denial and revocation of enrollment and certainly not on the grounds articulated in §§ 424.530(a)(15) and 424.535(a)(22). The commenters further stated that section 1866(j)(2) of the Act, which describes required and optional elements of the provider enrollment screening process, does not address denials and revocations. Accordingly, the commenters asserted that CMS cannot rely upon section 1866(j)(1)(A) (or, for that matter, sections 1102 and 1871) as authority for §§ 424.530(a)(15) and 424.535(a)(22) and must therefore withdraw these two proposed regulatory provisions.

Response: We disagree with the commenters. In previously establishing a significant number of our denial and revocation reasons under §§ 424.530(a) and 424.535(a), we interpreted the term ''efficient administration'' as giving CMS authority under sections 1102 and 1871 of the Act to take steps to safeguard the integrity of the Medicare program and to protect beneficiaries, an interpretation that we believe also permits us to finalize §§ 424.530(a)(15) and 424.535(a)(22). These regulations are needed to address the numerous enrollment scenarios involving problematic providers that can arise (and have arisen) over the course of our administration of the program.

With respect to section 1866(j)(1)(A) of the Act, we have never viewed the provider enrollment process as being restricted to the steps involved in screening initial applicants. The process consists of much more than that, including, but not limited to, ensuring that an enrolled provider or supplier maintains compliance with all applicable Medicare policies. The same is true concerning section 1866(j)(2) of the Act. Provider enrollment screening continues after a provider or supplier is enrolled in the form of, for example, the revalidation process under § 424.515 (which helps confirm whether an enrolled provider still meets all Medicare requirements) and monthly checks against the OIG's List of Excluded Individuals and Entities. It is not limited to the screening of initial applicants. Section 1866(j)(2)(D) of the Act, in other words, discusses both the screening of currently enrolled providers and suppliers and the screening of providers and suppliers as they periodically revalidate their enrollment. In summary, we respectfully do not believe that sections 1866(j)(1)(A) and 1866(j)(2) of the Act become inapplicable once a provider is enrolled.

We also disagree that sections 1102 and 1871 of the Act do not permit CMS to establish revocation authorities, especially regarding patient harm. Were we to accept this contention, enrolled providers and suppliers could engage in egregious behavior without fear of repercussions because CMS would have no authority to remove them from Medicare. We do not believe that Congress, in enacting these statutes, intended such a result.

Comment: Several commenters stated that § 424.535(a)(22) does not include any criteria or process by which CMS would determine when it would revoke enrollment, thus raising the potential for arbitrary decisions. For example, the commenters stated that: (1) Physicians with similar actions taken against them could be treated differently; and (2) state medical statutes and medical board review standards vary considerably. The commenters stated that treating all activities as being similar is inappropriate.

Response: We disagree that § 424.535(a)(22) lacks appropriate criteria. To the contrary, and as stated previously, both §§ 424.530(a)(15) and 424.535(a)(22) list specific factors that CMS must consider in its determinations. The factors account for our recognition that all cases, state oversight boards, and statutes are indeed different while furnishing enough clarity to help ensure that relatively similar cases are handled in as uniform a manner as possible.

Comment: Numerous commenters stated that state oversight boards, not the federal government, are the appropriate entities for monitoring and disciplining physicians and, if warranted, restricting their authority to treat patients. The commenters stated that the proper punishment for physicians who have violated the law is to take action against his or her license; if the state upholds his or her right to practice, he or she should be allowed to remain enrolled in Medicare assuming all other program requirements are met. The commenters added that the patient harm provisions: (1) Represent an unprecedented overreach of the federal government's authority; (2) constitute an unwarranted intrusion into matters best left to states; (3) inappropriately substitute CMS' lack of clinical expertise for the expertise of the state oversight board's medical professionals; and (4) involve a mere after-the-fact desk review of the state oversight board's well-informed decisions. Several other commenters stated that our statement in the proposed rule that CMS (rather than state oversight boards) is ultimately responsible for the protection of Medicare beneficiaries is inaccurate; instead, the commenters stated, state oversight boards are responsible for ensuring the health, safety, and welfare of the state's residents (which include Medicare beneficiaries) through the enforcement of laws governing health care providers.

Response: We certainly recognize and appreciate the very crucial role that state oversight boards perform in protecting the health of patients, enforcing medical laws, and overseeing physician and practitioner care. However, we do not believe these functions are exclusive to states. CMS indeed has oversight responsibility for the Medicare program, and this includes safeguarding the welfare of individuals who receive benefits under this program. State review of licensed physicians and other eligible professionals is a function entirely different from the federal government's administration of Medicare. Given this, we respectfully submit that CMS is not and should not be prohibited from taking action against a Medicare provider merely because the state oversight board may disagree with such action. That is, while we generally give great deference to state oversight boards and their judgments, there could be instances where CMS, in its oversight of Medicare, feels compelled to review a matter potentially impacting the Trust Funds and those beneficiaries whose health care is covered thereby. This overriding principle, rather than any desire to interfere with or usurp the decisions of state oversight boards, lies behind our patient harm provisions.

Comment: A number of commenters expressed concern that our proposed patient harm provisions were discussed in a section of the proposed rule that also discussed OTP enrollment. The commenters stated that many provider organizations: (1) Were unaware of the provisions' presence; or (2) might believe that the provisions only applied to OTP physicians or other eligible professionals, rather than to all types of physicians and other eligible professionals or only to high-risk providers. Another commenter stated

that CMS should accordingly withdraw these provisions and re-propose them in a stand-alone rule to ensure an adequate opportunity for notice and comment. An additional commenter requested that CMS delay these provisions until it works with the provider community to help the latter understand the provisions' full implications.

Response: Considering that §§ 424.530(a)(15) and 424.535(a)(22) are enrollment provisions, we maintain that grouping these provisions with those pertaining to OTP enrollment was the most sensible approach. We note that the titles of both the rule and the enrollment subsection clearly indicated that enrollment policies pertaining to patient harm were included therein. We also explicitly stated that the patient harm provisions applied to all types of physicians and other eligible professionals (not merely those associated with OTPs) and gave no indication that the provisions were limited to high-risk providers. Given the number of comments we received on §§ 424.530(a)(15) and 424.535(a)(22), we believe that sufficient public notice was furnished regarding these provisions.

Comment: One commenter stated that the list of possible actions against a physician that potentially fall under §§ 424.530(a)(15) and 424.535(a)(22) is extensive. The commenter questioned how these actions would be used or weighted in CMS' determination.

Response: As previously mentioned, the particular action will be considered through CMS' analysis of the factors in §§ 424.530(a)(15) and 424.535(a)(22).

Comment: Several commenters requested clarification as to whether: (1) CMS or the MAC would make § 424.535(a)(22) revocation determinations; and (2) the affected physician or other eligible professional will be able to review the case. The commenters expressed concern that CMS would take action under the patient harm provisions without reviewing the underlying evidence or analysis regarding the prior action or having sufficient data to make a fair and thorough determination; such information, the commenters stated, would include, but not be limited to, the genesis of the complaint, the veracity of the allegations, and the rationale for (and deliberations involved in) the state's decision or the reasoning behind any settlement. To avoid this prospect, the commenters recommended that some form of due process be considered before enrollment is denied or revoked; this would help ensure that CMS has all the facts and circumstances available. For instance, they noted that state oversight boards permit the physician or practitioner to offer rebuttal evidence and to respond to the proposed adverse action before the board renders its decision. Stating that CMS did not articulate a clear or adequate appeals process that ensures fairness for the provider, the commenters asserted that CMS should adopt the process outlined in the previous sentence.

Response: CMS, rather than an applicable CMS contractor, will typically make §§ 424.530(a)(15) and 424.535(a)(22) determinations. Yet, we do not exclude the possibility that an applicable CMS contractor could make a denial or revocation determination under §§ 424.530(a)(15) and 424.535(a)(22), respectively.

Appeal rights under part 498 will be provided. However, as with all other revocations under § 424.535, the affected physician or other eligible professional will be unable to review the case during our determination process. The reason for this longstanding policy is that we must be able to take prompt action, using our independent judgment, to halt potential threats to Medicare patients and the Trust Funds. We see no reason to exempt § 424.535(a)(22) situations from this practice. Merely because the grounds for revocation under § 424.535(a)(22) are different from those in other revocation reasons does not require that the affected party be able to formally review, comment on, and contest its potential § 424.535(a)(22) revocation before CMS is able to render a decision; indeed, instances of patient harm can represent a particularly serious danger to Medicare beneficiaries, thus requiring rapid measures on our part. We also reiterate that CMS is a federal agency and, as such, is not bound to utilize the same administrative processes and mechanisms that state oversight boards do.

Insofar as the risk of an insufficient record, CMS in all revocation cases ensures that it has enough information on hand to make a fair and well-informed determination. Such will be so with § 424.535(a)(22), too.

Comment: Several commenters stated that the patient harm provisions partially duplicate CMS' existing revocation authorities, such as, but not limited to: (1) § 424.535(a)(21), which permits revocation if a physician or other eligible professional has a pattern or practice of abusive ordering, certifying, referring, or prescribing that threatens the health and safety of Medicare beneficiaries; and (2) CMS' ability to revoke enrollment if the individual's medical license is revoked. The commenters stated that CMS should rely on these authorities, which already protect against egregious behavior, rather than finalize the patient harm provisions. The commenters added that if CMS believes it needs additional revocation authority to address specific behaviors, it should articulate those behaviors and propose a revocation reason that is appropriately defined and specifically targeted.

Response: We do not believe that §§ 424.530(a)(15) and 424.535(a)(22) duplicate our existing revocation authorities, for we currently have no provision that directly and specifically addresses and targets demonstrated cases of patient harm. Thus, we believe that §§ 424.530(a)(15) and 424.535(a)(22) are necessary.

Comment: While asserting that CMS should withdraw its patient harm provisions and instead work with industry stakeholders on solutions to its concerns, several commenters recommended that CMS at least consult state licensure boards, medical professional groups, and hospitals before finalizing its criteria. This would help ensure that the latter are applied in a fair and consistent fashion.

Response: We respectfully decline to delay finalization of these provisions. We believe they are needed for the reasons described previously in this rule. Nonetheless, we always welcome feedback from provider organizations and would be pleased, after this rule is published, to hear any remaining concerns they may have.

Comment: Several commenters sought clarification as to whether CMS will only consider those actions that have been fully adjudicated and complete, or also those still in progress. The commenters recommended the former approach.

Response: CMS will be able to take action under § 424.530(a)(15) or § 424.535(a)(22), as applicable, once a state oversight board reports a particular action or order pertaining to patient harm that CMS determines warrants denial or revocation action. However, if the action or order is later overturned, CMS will take reciprocal action, as appropriate, and rescind the denial or revocation.

Comment: Concerning our proposed definition of ''state oversight board'' in § 424.502, one commenter stated that regulatory boards exist for a variety of health professions and are not limited to medical boards. The commenter indicated that a more inclusive term than ''state oversight board'' would be, for example, ''regulatory board,'' ''state regulatory board,'' or ''state licensing board.''

Response: We recognize that different types of regulatory boards exist for multiple health professions. While we appreciate the commenter's suggested edits, we believe that the term ''state oversight board'' is broad enough to cover the variety of administrative bodies to which the commenter refers.

Comment: A commenter stated that a state-level action or IRO determination that occurred may not have any relation to a physician's or other eligible professional's participation in Medicare.

Response: If we are correctly understanding the commenter's contention, it is indeed possible that the action or IRO determination in question may not have involved the physician's or other eligible professional's treatment of a Medicare patient. However, if the physician or other eligible professional is enrolling or enrolled in Medicare, we believe we have an obligation to consider the potential impact on Medicare beneficiaries of the patient harm that lay behind the state action or IRO determination.

We also received a miscellaneous comment pertaining to the opt-out provisions covered in 42 CFR part 405, subpart D:

Comment: A commenter requested that CMS revise and revoke the requirements in, respectively, § 405.415(h) and (o) that state that private contracts between Medicare patients and physicians who have opted-out of Medicare must be re-signed every 2 years. The commenter stated that patients and physicians should have the flexibility to agree upon any mutually desired contract length. The commenter added that these contracts should be allowed to remain in effect as long as the physician remains opted-out of Medicare. These requested changes, the commenter stated, would reduce physician burden and eliminate confusion regarding the requirements in question.

Response: We appreciate this comment but believe it is outside the scope of this rule.

d. Final Improper Prescribing and Patient Harm Provisions

After reviewing the comments received, we are finalizing our proposed change to § 424.535(a)(14) and our proposed definition of ''state oversight board.'' For §§ 424.530(a)(15) and 424.535(a)(22), we are finalizing these provisions with the following exceptions:

- We are removing the following criteria from these provisions:

++ Required participation in rehabilitation or mental/behavioral health programs.

++ Required abstinence from drugs or alcohol and random drug testing.

- We are adding new paragraphs to these provisions that exclude from consideration those actions and orders restricted to: (1) Required participation in rehabilitation or mental/behavioral health programs; or (2) required abstinence from drugs or alcohol and random drug testing.
- We are also removing the criterion that reads: ''Any other information that CMS deems relevant to its determination.''

In addition, the introductory amendatory language for the proposed regulatory text for § 424.530(a)(15) stated, in part, that § 424.530(a)(12), (13), and (14) were being reserved. Similar introductory amendatory language for proposed § 424.535(a)(22) stated that § 424.535(a)(17) through (21) were being reserved. These statements are no longer applicable. The provisions in question are not being reserved. Therefore, we are removing these references. The only amendment to § 424.530 is the addition of paragraph (a)(15); the lone amendment to § 424.535 is the addition of paragraph (a)(22).

I. Deferring to State Scope of Practice Requirements

When the Medicare program was signed into law in 1965, most skilled medical professional services in the United States were provided by physicians, with the assistance of nurses. Over the decades, the medical professional field has diversified and allowed for a wider range of certifications and specialties, including the establishment of mid-level practitioners such as nurse practitioners (NPs) and physician assistants (PAs). These practitioners are also known as advanced practice providers (APPs) or nonphysician practitioners (NPPs). Medicare policies and regulations have been updated over recent years to allow APPs or NPPs to provide services in Medicare-certified facilities within the extent of their scope of practice as defined by state law. In recognition of the qualifications of these practitioners, we seek to continue this effort.

1. Ambulatory Surgical Centers

a. Background

Ambulatory surgical centers (ASCs), as defined at 42 CFR 416.2, are distinct entities that operate exclusively for the purpose of providing surgical services to patients not requiring hospitalization, in which the expected duration of services would not exceed 24 hours following admission. The surgical services performed at ASCs are scheduled, primarily elective, non-life-threatening procedures that can be safely performed in an outpatient setting. Currently, there are approximately 5,800 Medicare certified ASCs in the United States.

Section 1832(a)(2)(F)(i) of the Act specifies that ASCs must meet health, safety, and other requirements specified by the Secretary in order to participate in Medicare. The Secretary is responsible for ensuring that the ASC Conditions for Coverage (CfCs) protect the health and safety of all individuals treated by ASCs, whether they are Medicare beneficiaries or other patients. The ASC regulations were established in the ''Medicare Program; Ambulatory Surgical Services'' final rule published in the August 5, 1982 **Federal Register** (47 FR 34082), and have since been amended several times.

The regulations for Medicare and Medicaid participating ASCs are set forth at 42 CFR part 416. Section 416.42, ''Condition for coverage-Surgical services'', states that surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

Currently, the ASC CfCs have two conditions that include patient assessment requirements for patients having surgery in an ASC, those are anesthetic risk and pre-surgery evaluation, and pre-discharge evaluation. In the November 18, 2008 final rule, ''Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates final rule (73 FR 68502), we revised some existing standards and created some new requirements. One of the new conditions added in 2008 was § 416.52, ''Conditions for coverage—Patient admission, assessment and discharge''. This condition sets standards pertaining to patient pre-surgical assessment, post-surgical assessment, and discharge requirements that must be met before patients leave the ASC. Specifically, the discharge requirements at § 416.52(b)(1) require that a post-surgical assessment be completed by a physician, or other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable state health and safety laws, standards of practice, and ASC policy. The other discharge condition, at § 416.42(a)(2), also finalized in the November 18, 2008 final rule, allows anesthetists, in addition to physicians, to evaluate each patient for proper anesthesia recovery. The requirement at

§ 416.42(a)(1) requires a physician to examine the patient immediately before surgery to evaluate the risk of anesthesia and the procedure to be performed.

Through various inquiries from ASCs and communication with CMS by industry associations, we have received many requests to align the anesthetic risk and pre-surgery evaluation standard at § 416.42(a)(1) with the pre-discharge standard at § 416.42(a)(2) by allowing an anesthetist, in addition to a physician, to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure. For those ASCs that utilize non-physician anesthetists, also known as certified registered nurse anesthetists (CRNAs), this revision would allow them to perform the anesthetic risk and evaluation on the patient they are anesthetizing for the procedure to be performed by the physician. CRNAs are advanced practice registered nurses who administer more than 43 million anesthetics to patients each year in the United States. CRNAs are Medicare Part B providers and since 1989, have billed Medicare directly for 100 percent of the PFS amount for services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in most rural hospitals. A study published by Nursing Economic$ in May/June 2010, found that CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measureable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.[105] We believe this alignment provides for continuity of care for the patient and allows the patient's anesthesia professional to have familiarity with the patient's health characteristics and medical history.

b. Provisions

We proposed to revise § 416.42(a), Surgical services, to allow either a physician or an anesthetist, as defined at § 410.69(b), to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure to be performed. By amending the CfCs to allow an anesthetist or a physician to examine and evaluate the patient before surgery for anesthesia risk and the planned procedure risk, we will be allowing ASC patient evaluations to be more consistent by using the option for the same clinician to complete both pre- and post-procedure anesthesia evaluations.

This change is a continuation of our efforts to reduce regulatory burden. It will increase supplier flexibility and reduce burden, while allowing qualified clinicians to focus on providing high-quality healthcare to their patients. We also requested comments and suggestions for other ASC requirements that could be revised to allow greater flexibility in the use of NPPs, and reduce burden while maintaining high quality health care.

We received approximately 4,000 public comments on the proposed ASC requirements to allow CRNAs to perform pre-surgical patient evaluations and other potential revisions that could allow greater flexibility in the use of NPPs, and reduce burden while maintaining high quality health care. Commenters included healthcare industry associations, clinician associations, individual ASCs and clinicians, and the vast majority of comments were form letters. The following is a summary of the comments we received and our responses.

Comment: The comments addressing the proposed regulatory change to allow either a physician or an anesthetist to examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed were split between support and opposition. However, the majority of commenters supported the change to allow anesthetists, in addition to physicians, to evaluate patients before surgery for anesthesia risk. The commenters supporting the proposed option for an anesthetist noted the change would reduce burden, reduce healthcare costs, align the pre-surgical anesthetic evaluation with the post-surgical evaluation standard, and better enable the patient's anesthesia professional to have familiarity with the patient's health characteristics and medical history. The commenters noted that in many facilities, CRNAs may be the only anesthesia providers. In addition, the support comments were predominantly silent in addressing the risk evaluation of the planned surgical procedure. The commenters that opposed the addition of an anesthetist stated they believe it would jeopardize the safety of patients, that only physicians possess the medical background to assess the patient in an objective, evidence-based and patient-centric way, and that nurse anesthetist training is limited to anesthesia care delivery, not risk assessment, diagnosis, or medical decision making outside the scope of an anesthetic.

Other commenters agreed with the proposed change to allow an anesthetist to complete the pre-surgical evaluation to align the pre and post-surgical evaluation standards and further suggested modifications to the proposed regulation text to clarify the roles of the anesthetist and the physician in the pre-surgical evaluation standard. They suggested a modification to the text that would clarify the anesthesia provider pre-surgical anesthesia evaluation responsibilities and the pre-surgical evaluation by the physician to determine the patient's capability to undergo the procedure safely.

Response: Based on the comments we received, it seems commenters are addressing two specific, separate patient risk evaluations in the proposed § 416.42(a)(1). The majority of commenters agreed with the proposed change to allow anesthetists the ability to conduct the pre-surgical anesthesia risk evaluation. The commenters who opposed the change stated that the evaluation of the patient's ability to tolerate the overall procedure should remain with the physician, and we also agree. We believe it is beneficial and appropriate to clarify in regulation text the separate evaluations and who must be responsible for them. The commenters supporting the proposed change primarily address the anesthetists' ability to perform the anesthesia risk pre-surgical assessment, aligning with the post-surgical anesthesia evaluation required by regulations that currently allow a physician or an anesthetist as defined at § 410.69(b). Additional evidence regarding anesthesia safety was published in an August 2010 research study in *Health Affairs* that reported findings showing no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.[106] Two additional research articles, studying anesthesia complications and safety, also found no differences in care between nurse anesthetists and physician anesthesiologists.[107] [108]

[105] Paul F. Hogan et. al, ''Cost Effectiveness Analysis of Anesthesia Providers.'' Nursing Economic$. 2010; 28:159–169.

[106] B. Dulisse and J. Cromwell, ''No Harm Found When Nurse Anesthetists Work Without Physician Supervision.'' Health Affairs. 2010; 29: 1469–1475.

[107] Lewis SR, Nicholson A, Smith AF, Alderson P. Physician anesthetists versus non-physician providers of anesthesia for surgical patients. Cochrane Database of Systematic Reviews 2014, Issue 7. Art. No.: CD010357.

[108] Negusa B et al. Scope of practice laws and anesthesia complications: No measurable impact of certified registered nurse anesthetists expanded scope of practice on anesthesia-related complications. Medical Care June 2016, *http://journals.laww.com/lww-medicalcare/Abstract/*

Continued

We believe the physician is the appropriate practitioner to perform the clinical assessment for the overall procedure, taking into account underlying patient comorbidities and all aspects of the surgical procedure to be performed to ensure a successful and optimal outcome of the planned procedure in an ASC setting. The physician or anesthetist, in tandem with the physician evaluating the procedure to be performed, would be evaluating the risk of anesthesia and the ability for the patient to tolerate the planned level of anesthesia.

Based on comments we received, we are modifying the proposed change at § 416.42(a)(1) to clarify that there are two components to any pre-procedure evaluation and require that, immediately before surgery, a physician must examine the patient to evaluate the risk of the procedure to be performed, and a physician or anesthetist must examine the patient to evaluate the risk of anesthesia. A physician may perform both parts of the pre-procedure evaluation. As noted in the proposed rule, we believe this change to the pre-surgical patient anesthetic risk evaluation provides alignment within the regulations, continuity of care for the patient, and better ensures the patient's anesthesia professional's familiarity with the patient's health characteristics and medical history. It will also reduce burden on ASCs by allowing additional members of the medical team to conduct pre-surgical anesthesia evaluations.

2. Hospice

a. Background

Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual, and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Medicare regulations define ''palliative care'' as patient and family centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice (42 CFR 418.3). The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. The hospice interdisciplinary group works with the patient, family, caregivers, and the patient's attending physician (if any) to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and their families and caregivers about changes in their condition. The care plan will shift over time to meet the changing needs of the patient, family, and caregiver(s) as the patient approaches the end of life.

The regulations for Medicare and Medicaid participating hospices are set forth at 42 CFR part 418. Section 418.3 defines the term ''attending physician'' as being a doctor of medicine or osteopathy, an NP, or a PA in accordance with the statutory definition of an attending physician at section 1861(dd)(3)(B) of the Act. Section 51006 of the Bipartisan Budget Act of 2018 revised the statute to add PAs to the statutory definition of the hospice attending physician for services furnished on or after January 1, 2019. As a result, PAs were added to the definition of a hospice attending physician as part of the ''Medicare Program; FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements'' final rule which was published in the August 6, 2018 **Federal Register** (83 FR 38622, 38634) (hereinafter referred to as the ''FY 2019 Hospice final rule''.)

The role of the patient's attending physician, if the patient has one, is to provide a longitudinal perspective on the patient's course of illness, care preferences, psychosocial dynamics, and generally assist in assuring continuity of care as the patient moves from the traditional curative care model to hospice's palliative care model. The attending physician is not meant to be a person offered by, selected by, or appointed by the hospice when the patient elects to receive hospice care. Section 418.64(a) of the hospice regulations requires the hospice to provide physician services to meet the patient's hospice-related needs and all other care needs to the extent that those needs are not met by the patient's attending physician. Thus, if a patient does not have an attending physician relationship prior to electing hospice care, or if the patient's attending physician chooses to not participate in the patient's care after the patient elects to receive hospice care, then the hospice is already well-suited to provide physician care to meet all of the patient's needs as part of the Medicare hospice benefit. If the patient has an attending physician relationship prior to electing hospice care and that attending physician chooses to continue to be involved in the patient's care during the period of time when hospice care is provided, the role of the attending physician is to consult with the hospice interdisciplinary group (also known as the interdisciplinary team) as described in § 418.56, and to furnish care for conditions determined by the hospice interdisciplinary group to be unrelated to the terminal prognosis. The hospice interdisciplinary group must include the following members of the hospice's staff: A physician; a nurse; a social worker; and a counselor. The interdisciplinary group may also include other members based on the specific services that the patient receives, such as hospice aides and speech language pathologists. The hospice interdisciplinary group, as a whole, in consultation with the patient's attending physician (if any), the patient, and the patient's family and caregivers, are responsible for determining the course of the patient's hospice care and establishing the individualized plan of care for the patient that is used to guide the delivery of holistic hospice services and interventions, both medical and non-medical in nature.

b. Provisions

In the role of a consultant to the hospice interdisciplinary group, the hospice patient's chosen attending physician may, at times, write orders for services and medications as they relate to treating conditions determined to be unrelated to the patient's terminal prognosis. The law allows for circumstances in which services needed by a hospice beneficiary would be completely unrelated to the terminal prognosis, but we believe that this situation would be the rare exception rather than the norm. Section 418.56(e) requires hospices to coordinate care with other providers who are also furnishing care to the hospice patient, including the patient's attending physician who is providing care for conditions determined by the hospice interdisciplinary group to be unrelated to the patient's terminal prognosis. As part of this coordination of care, it is possible that hospices may receive orders from the attending physician for drugs that are unrelated to the patient's terminal prognosis.

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The FY 2019 Hospice final rule amended the regulatory definition of ''attending physician,'' as required by the statute, to include ''physician assistant.'' Following publication of the FY 2019 Hospice final rule, stakeholders raised concerns regarding the requirements of § 418.106(b). As currently written, hospices may not accept orders for drugs from attending physicians who are PAs because § 418.106(b) specifies that hospices may accept drug orders from physicians and NPs only. This regulatory requirement may impede proper care coordination between hospices and attending physicians who are PAs, and we believe that it should be revised.

Therefore, we proposed to revise § 418.106(b)(1) to permit a hospice to accept drug orders from a physician, NP, or PA. We proposed that the PA must be an individual acting within his or her state scope of practice requirements and hospice policy. We also proposed that the PA must be the patient's attending physician, and that he or she may not have an employment or contractual arrangement with the hospice. The role of physicians and NPs as hospice employees and contractors is clearly defined in the hospice CoPs; however, the CoPs do not address the role of PAs because the statute does not include PA services as being part of the Medicare hospice benefit. Therefore, we believe that it is necessary to limit the hospice CoPs to accepting only those orders from PAs that are generated outside of the hospice's operations.

To more fully understand the current and future role of NPPs, including PAs, in hospice care and the hospice CoPs, we requested public comment on the following questions:

- What is the role of a NPP in delivering safe and effective hospice care to patients? What duties should they perform? What is their role within the hospice interdisciplinary group and how is it distinct from the role of the physician, nurse, social work, and counseling members of the group?
- Nursing services are a required core service within the Hospice benefit, as provided in section 1861(dd)(B)(i) of the Act, which resulted in the defined role for NPs in the Hospice COPs. Should other NPPs also be considered core services on par with NP services? If not, how should other NPP services be classified?
- In light of diverse existing state supervision requirements, how should NPP services be supervised? Should this responsibility be part of the role of the hospice medical director or other physicians employed by or under contract with the hospice? What constitutes adequate supervision, particularly when the NPP and supervising physician are located in different offices, such as hospice multiple locations?
- What requirements and timeframes currently exist at the state level for physician co-signatures of NPP orders? Are these existing requirements appropriate for the hospice clinical record? If not, what requirements are appropriate for the hospice clinical record?
- What are the essential personnel requirements for PAs and other NPPs?

We received public comments on the proposed regulatory change to allow hospices to accept medication orders from PAs who are attending physicians as chosen by the patient that do not have an employment or contractual relationship with the hospice. We also received information in response to our solicitation for public comments regarding the current and future role of NPPs, including PAs, in hospice care and the hospice CoPs. The following is a summary of the comments we received and our responses.

Comment: All comments regarding the proposed regulatory change to allow hospices to accept medication orders from PAs who are attending physicians as chosen by the patient that do not have an employment or contractual relationship with the hospice noted support for allowing hospice to accept drug orders from such PAs. Some commenters suggested that hospices should be allowed to accept orders from PAs employed by or under arrangement with the hospice.

Response: We agree with the commenters that this proposed change is appropriate to assure care coordination between attending physicians who are PAs and hospices, and we are finalizing the proposal without change. We do not agree that PAs employed by or under arrangement with the hospice should be included in this rule, as such piecemeal inclusion without complimentary regulations to establish the scope of PA services in hospices may create patient safety and program vulnerabilities. It is clear from the comments that a notable portion of the physician assistant and hospice communities view the role of the physician assistant as an acceptable substitute for hospice physicians, which is not in accordance with current statutory provisions. We believe that this disconnect between public perception of the role of the PA and the requirements of the statute necessitates rulemaking to clearly set forth what is and is not permissible. We will consider this suggestion for future rulemaking.

Comment: A few commenters disagreed with the idea that attending physicians who are physician assistants should be limited to prescribing only those medications or therapies that are not related to the terminal prognosis.

Response: We did not propose, nor are we finalizing, any such limitations. Attending physicians, regardless of their qualifications, are consultants to the hospice interdisciplinary group. It is the hospice interdisciplinary group, comprised of, at minimum, a physician, nurse, social worker, and counselor in accordance with the requirements set forth in section 1861(dd)(2)(B)(i) of the Act, that is responsible for determining the content of the patient's hospice plan of care and issuing all necessary orders to implement that plan of care. Given that: (1) Each interdisciplinary group contains, at minimum, a physician member employed by or under arrangement with the hospice actively involved in the patient's care at all times, (2) hospice physician services must be available at all times, and (3) the physician member has the authority to write all orders necessary to implement the plan of care, the need for an attending physician outside of the hospice to write orders related to implementing the hospice plan of care should be rare.

Comment: The majority of the commenters submitted information regarding the current and future role of NPPs, including PAs and advanced practice registered nurses (APRNs), in hospice care and the hospice CoPs.

Response: We thank the commenters for sharing this information, and will take it into consideration when developing all future hospice CoPs related to the role of NPPs.

Comment: One commenter posed the following question: There are a number of PAs in palliative care that are employed or under contract with the parent company that also operates the hospice. Would CMS consider these PAs to be an employee of the hospice if everyone operates under the same tax identification number?

Response: Section 418.3, Definitions, of the hospice CoPs defines an employee as a person who: (1) Works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf; (2) if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or (3) is a volunteer under the jurisdiction of the hospice. If a PA is assigned by the ''parent company'' to the hospice, then the PA is considered to be an ''employee'' of the hospice.

Comment: Some commenters made suggestions related to hospice payment requirements, CMS manuals, and statutory requirements that are not within the scope of our proposal to revise the hospice CoPs or within our regulatory authority.

Response: We have shared these out of scope comments with the appropriate CMS stakeholders.

In accordance with public comments, we are finalizing the change at § 418.106(b)(1) as proposed.

J. Advisory Opinions on the Application of the Physician Self-Referral Law

1. Statutory and Regulatory Background

Section 4314 of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted August 5, 1997), added section 1877(g)(6) to the Act. Section 1877(g)(6) of the Act requires the Secretary to issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. On January 9, 1998, the Secretary issued a final rule with comment period in the **Federal Register** to implement and interpret section 1877(g)(6) of the Act (the 1998 advisory opinion rule). (See Medicare Program; Physicians' Referrals; Issuance of Advisory Opinions (63 FR 1646).) The regulations are codified in §§ 411.370 through 411.389 (the physician self-referral advisory opinion regulations).

Section 1877(g)(6)(A) of the Act states that each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion. Section 1877(g)(6)(B) of the Act requires the Secretary, in issuing advisory opinions regarding the physician self-referral law, to apply the rules in paragraphs (b)(3) and (4) of section 1128D of the Act, to the extent practicable. This paragraph also requires the Secretary to take into account the regulations promulgated under paragraph (b)(5) of section 1128D of the Act.

Section 1128D of the Act was added to the statute by section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, effective August 21, 1996). Among other things, section 1128D of the Act requires the Secretary, in consultation with the Attorney General, to issue written advisory opinions as to specified matters related to the anti-kickback statute in section 1128B(b) of the Act, the safe harbor provisions in § 1001.952, and other provisions of the Act under the authority of the Office of Inspector General (OIG). To implement and interpret section 1128D of the Act, OIG issued an interim final rule with comment period in the February 19, 1997 **Federal Register** entitled Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG (62 FR 7350), revised and clarified its regulations in the July 16, 1998 **Federal Register** (68 FR 38311), and updated its regulations in a final rule published in the July 17, 2008 **Federal Register** that solely revised certain procedural requirements for submitting payments for advisory opinion costs (73 FR 40982) (collectively, the OIG advisory opinion rule). The regulations are codified in part 1008 of this title of the Code of Federal Regulations (the OIG advisory opinion regulations).

Section 1128D(b)(3) of the Act prohibits the Secretary from addressing in an advisory opinion whether: (1) Fair market value shall be or was paid or received for any goods, services, or property; or (2) an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986. In the 1998 advisory opinion rule, we incorporated these provisions into the physician self-referral law regulations (63 FR 1646). Section 1128D(b)(4)(A) of the Act states that an advisory opinion related to OIG authorities is binding as to the Secretary and the party or parties requesting the opinion. This section is redundant of the provision in section 1877(g)(6)(A) of the Act, and therefore, not incorporated into the physician self-referral law advisory opinion regulations. Section 1128D(b)(4)(B) of the Act provides that the failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or 1128B of the Act. We incorporated section 1128D(b)(4)(B) of the Act in the physician self-referral regulations at § 411.388.

As discussed previously, section 1877(g)(6)(B) of the Act requires the Secretary, to the extent practicable, to take into account the regulations issued under the authority of section 1128D(b)(5) of the Act (that is, the OIG advisory opinion regulations). Section 1128D(b)(5)(A) of the Act requires that the OIG advisory opinion regulations must provide for: (1) The procedure to be followed by a party applying for an advisory opinion; (2) the procedure to be followed by the Secretary in responding to a request for an advisory opinion; (3) the interval in which the Secretary will respond; (4) the reasonable fee to be charged to the party requesting an advisory opinion; and (5) the manner in which advisory opinions will be made available to the public. We interpret the Congress' directive to take into account the OIG regulations to mean that we should use the OIG regulations as our model, but that we are not bound to follow them (63 FR 1647). Nonetheless, in the 1998 advisory opinion rule, we largely adopted OIG's approach to issuing advisory opinions, stating that we intend for physician self-referral law advisory opinions to provide the public with meaningful advice regarding whether, based on specific facts, a physician's referral for a designated health service (other than a clinical laboratory service) is prohibited under section 1877 of the Act (63 FR 1648).

2. Revisions to the 1998 Advisory Opinion Process and Regulations

In the June 25, 2018 **Federal Register**, we published a Request for Information Regarding the Physician Self-Referral Law (83 FR 29524) (June 2018 CMS RFI) that sought recommendations from the public on how to address any undue impact and burden of the physician self-referral statute and regulations. Although we did not specifically request comments on the physician self-referral advisory opinion regulations, we received a number of comments urging that CMS reconsider its approach to advisory opinions and transform the process such that the regulated industry may obtain expeditious guidance on whether a physician's referrals to an entity with which he or she has a financial relationship would be prohibited under section 1877 of the Act. These commenters stated their belief that the current advisory opinion process could be improved. Some commenters also stated that the process is too restrictive, noting that CMS has placed what the commenters see as unreasonable limits on the types of questions that qualify for an advisory opinion (for example, CMS will not issue an advisory opinion where the arrangement at issue is hypothetical and does not issue advisory opinions on general questions of interpretation), and that physician self-referral law advisory opinions apply only to the specific circumstances of the requestor. These commenters asserted that the OIG's advisory opinion process, upon which the physician self-referral law advisory opinion process is modeled, is inappropriate as applied to a payment statute, noting that OIG opines on matters related to a felony criminal statute, whereas the physician self-referral law, by contrast, is a payment rule without a *mens rea* requirement.

Some commenters highlighted the complexity of the physician self-referral regulations, the strict liability nature of the physician self-referral law, and the need for certainty before arrangements are initiated and claims submitted as reasons why an advisory opinion process related to a felony criminal statute is inappropriate for the physician self-referral law. Other commenters asserted that the process is arduous and inefficient. These commenters noted that the advisory opinion process can extend beyond the 90-day timeframe provided for at § 411.380 and asserted that it lags behind the OIG process in terms of efficiency.

In designing its advisory opinion process, OIG stated that it carefully balanced stakeholders' desire for an accessible process and meaningful and informed opinions with its need to closely scrutinize arrangements to insure that requesting parties are not inappropriately granted protection from sanctions. (63 FR 38312 through 38313). We appreciate that there are important differences between the physician self-referral law, a strict liability statute designed to prevent payment for services where referrals are affected by inherent financial conflicts of interest, and the anti-kickback statute, which is a criminal law designed to prosecute intentional acts of fraud and abuse.

More than 20 years have passed since the 1998 advisory opinion regulations were issued. In those 20 years, we issued 31 advisory opinions,[109] 15 of which addressed the 18-month moratorium on physician self-referrals to specialty hospitals in which they have an ownership or investment interest. In light of the comments received on the RFI, we undertook a fresh review of the 1998 advisory opinion process. We agree that it is important to have an accessible process that produces meaningful opinions on the applicability of section 1877 of the Act, especially in light of the perceived complexity of the physician self-referral regulations, including the requirements of the various exceptions and the key terminology applicable to many of the exceptions. We recognize that our current advisory opinion process has not been widely utilized by stakeholders and has resulted in few opinions being issued to date. Accordingly, we reviewed our advisory opinion regulations in an effort to identify limitations and restrictions that may be unnecessarily serving as an obstacle to a more robust advisory opinion process.

Failure to satisfy the requirements of an exception to the physician self-referral law carries significant consequences, regardless of a party's intent.[110] The safe harbors under the anti-kickback statute are voluntary, and the failure of an arrangement to fit squarely within a safe harbor does not *automatically* mean that the arrangement violates the anti-kickback statute. By contrast, the physician self-referral law prohibits a physician's referral if there is a financial relationship that does not satisfy the requirements of one of the enumerated exceptions. In other words, the physician self-referral law is a strict liability law, and parties that act in good faith may nonetheless face significant financial exposure if they misunderstand or misapply the law's exceptions.

Regulated parties' desire for certainty must be balanced with CMS' interest in maintaining the integrity of the advisory opinion process, and ensuring that it is not used to inappropriately shield improper financial arrangements. We believe that the risk of such misuse is acceptably low in this context because the advisory opinion authority at section 1877(g) of the Act is narrowly tailored. CMS can only issue favorable advisory opinions for arrangements that do not violate section 1877 of the Act, for example, because there is no referral for designated health services, there is no financial relationship, or the arrangement satisfies the requirements of an applicable exception. In contrast, OIG has issued favorable advisory opinions for arrangements that do not fit within a safe harbor where it has concluded, based on a totality of the facts and circumstances, that the arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute. CMS cannot similarly extend protection beyond the exceptions, so there is a structural limit on the scope of CMS' authority. Furthermore, a favorable advisory opinion from CMS does not immunize parties from liability under the anti-kickback statute.

We proposed changes that would both clarify the process and remove limitations and restrictions that might be unnecessarily serving as obstacles to a more robust advisory opinion process.

a. General

Comment: Commenters overwhelmingly supported the proposed modifications to the advisory opinion regulations, and many stated that the modifications, if finalized, would facilitate better understanding of how to comply with the law and help parties to nonabusive arrangements avoid the strict penalties that result from noncompliance. Some commenters stated that the proposed modifications to the advisory opinion process, if finalized, would assist in advancing innovation in care delivery by encouraging greater participation in value-based care and alternative payment arrangements. Several commenters agreed that the advisory opinion process for the physician self-referral law, a strict liability law, should not be identical to the advisory opinion process for the anti-kickback statute, a criminal law. Commenters expressed their hope that CMS would publish more advisory opinions in the future.

Response: We appreciate the commenters' support for our efforts to reform the advisory opinion process. We agree that a well-functioning advisory opinion process could aid in advancing two of the Department's top priorities—reducing regulatory burden on providers and encouraging adoption of alternative payment models and coordinated care arrangements. A faster and more robust advisory opinion process facilitates the shift to value-based care arrangements by providing more guidance for parties trying to understand how the physician self-referral law applies in an evolving and innovative marketplace. This will help to reduce provider burden by providing insight into what does and does not comply with the law, which encourages innovation.

Comment: Several commenters who were generally supportive of the proposed modifications to the advisory opinion process also stated that changes to the 1998 advisory opinion rule should not further develop or create additional abusive self-referring arrangements.

Response: This final rule does not change the number or scope of exceptions from the physician self-referral prohibition. This final rule merely updates the process for issuing advisory opinions on whether certain fact patterns would result in a prohibited referral. Under the advisory opinion process, requestors must provide, among other information, sufficient detail about the arrangement

[109] These advisory opinions are available on CMS' website, at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisoryopinions.html.* This number does not include advisory opinion requests that were withdrawn.

[110] The CMS Voluntary Self-Referral Disclosure Protocol (SRDP) allows providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute. Under the SRDP, CMS may reduce the amount due and owing for violations of section 1877 of the Act. Information about the SRDP can be found at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-Voluntary-Self-Referral-Disclosure-Protocol.pdf.*

and the named parties to the arrangement in its submission. The advisory opinion process involves communication with the requestor to ensure CMS has a clear understanding of the arrangement under review and the parties involved. We believe that the regulations governing the advisory opinion process contain sufficient guardrails to limit the risk of improper use of the advisory opinion process.

b. Matters Subject to Advisory Opinions (§ 411.370)

Section 1877(g)(6) of the Act requires the Secretary to issue advisory opinions concerning ''whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section.'' In accordance with section 1877(g)(6)(B) of the Act, CMS adopted in regulation rules mirroring the requirements in paragraphs (b)(3) and (4) of section 1128D of the Act, which prohibit OIG from opining on whether an arrangement is fair market value and whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code. In addition to these restrictions on matters that are not subject to advisory opinions, our current regulation at § 411.370(b)(1) states that CMS does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties. When explaining this regulation, we stated that we interpret section 1877(g)(6) of the Act to allow for opinions on specific referrals involving physicians in specific situations (63 FR 1649). We also noted our reasons for avoiding opinions on generalized arrangements, stating that it would not be possible for an advisory opinion to reliably identify all the possible hypothetical factors that might lead to different results.

(i) Requests That Present a General Question of Interpretation or Pose a Hypothetical Situation

Under our current regulations, we accept requests for advisory opinions that involve existing arrangements, as well as requests that involve arrangements into which the requestor plans to enter. While we did not propose an expansion of the scope of advisory opinion requests, we solicited comments on whether we should do so in the future. We proposed clarifications to § 411.370(b) regarding matters that qualify for advisory opinions and the parties that may request them. Specifically, we proposed to clarify that the request for an advisory opinion must ''relate to'' (rather than ''involve'') an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. Requestors continue to be obligated to disclose all facts relevant to the arrangement for which an advisory opinion is sought. We also proposed revisions to the regulation text for grammatical purposes.

The following is a summary of the comments we received on the above proposals and our responses.

Comment: Commenters generally supported the clarification that an advisory opinion request must ''relate to,'' rather than ''involve,'' an arrangement that is existing or into which the requestor plans to enter, although at least one commenter suggested that CMS not finalize this proposed clarification, based on the perception that it will not serve to decrease the volume of information that requestors will need to provide to CMS.

Response: We are finalizing the proposal to consider questions that ''relate to'' existing or planned arrangements. The modification is intended to provide further clarity on existing physician self-referral law advisory opinion policy. It is not intended to lessen the volume of information submitted, nor expand the scope of the advisory opinion process, but rather, to more precisely capture the appropriate scope of advisory opinion requests. As discussed further below, we will consider all complete requests that relate to either an existing or planned arrangement (that is, requests that describe a specific arrangement with sufficient detail).

Comment: A number of commenters urged CMS to further expand the matters subject to advisory opinions to include requests that present a general question of interpretation or pose a hypothetical situation. These commenters suggested that this would provide needed clarification for providers, would help reduce confusion around compliance with the physician self-referral law, and would help reduce the administrative burden of compliance, especially for small and rural providers. Several of these commenters wanted the flexibility to request an advisory opinion before spending the significant time and resources required to draft and formalize proposed arrangements. Others cited concerns that if they wait to seek an advisory opinion until after an arrangement is in place, they risk being found to be out of compliance and could face penalties.

Many commenters also acknowledged CMS' concern that expanding advisory opinions to cover hypothetical arrangements or general questions of interpretation could significantly increase the volume of advisory opinion requests. However, these commenters suggested that CMS could institute guardrails to ensure only legitimate and complete requests are entering into the process, such as imposing additional fee requirements, or using improved technology and intake processes for requests.

One commenter stated that CMS should not reject an advisory opinion request on the grounds that it poses only a ''general question of interpretation,'' especially since the requestor has no opportunity to rebut CMS' determination. This commenter stated that the distinction between planned arrangements and general matters of interpretation is abstract and favors form over substance, and urged that the ''general question of interpretation'' restriction be deleted. This commenter also stated that the proposed rule's requirement for requestors to describe arrangements in a sufficient level of detail would provide a meaningful safeguard against misuse of the advisory opinion process.

Response: We continue to believe that the Secretary's obligation under section 1877(g)(6) of the Act to issue advisory opinions concerning whether a referral relating to designated health services is prohibited under this section limits the subject of advisory opinions to questions about a specific referral made by a physician in a specific financial relationship under specific facts and circumstances. It remains our position that requests regarding hypothetical facts or general questions of interpretation are not appropriate for an advisory opinion. Further, although we proposed a number of changes to improve the advisory opinion process for stakeholders, we believe that expanding the process to include such questions could overwhelm the agency. As such, we are not expanding the scope of the advisory opinion process to include hypothetical arrangements or general questions of interpretation.

However, based on comments received, we have reviewed the regulation's current terminology of a request ''present[ing] a general question of interpretation'' or ''pos[ing] a hypothetical situation,'' and acknowledge that these terms may lack sufficient clarity. Based on the comments received, there appears to be some confusion over how CMS distinguishes a planned arrangement—that is, a specific arrangement that does not yet exist but the requestor in good faith plans to enter—from a hypothetical

fact pattern or question of general interpretation. Therefore, we are removing this terminology at 11.370(b)(1).

We accept and issue advisory opinions that relate to existing arrangements or arrangements into which the requestor intends to enter if it receives a favorable advisory opinion. To issue an advisory opinion, the requestor must provide, among other information, sufficient detail about the arrangement and the parties to the arrangement, including identifying information about one or both of the parties to the arrangement. Thus, the universe of acceptable advisory opinions would not include requests for guidance that interprets the physician self-referral law generally, such as whether generic noncompete provisions take into account the volume or value of a physician's referrals. Nor would the universe include a request to opine, in the abstract, whether a variety of compensation methodologies take into account the volume or value of referrals. Although we do not consider an arrangement to be a per se hypothetical matter simply because the parties have not yet entered into the arrangement, there are some matters that would be inappropriate for advisory opinions. These include requests for an advisory opinion regarding whether a physician's referral is prohibited under section 1877 of the Act where the underlying financial arrangement between the physician and the entity to which he or she refers designated health services is otherwise illegal or impermissible. For example, we would not accept a request for an advisory opinion regarding whether a referral is permissible if the claim for the designated health services could not be billed to the Medicare program for some reason unrelated to the physician self-referral law. We have made modifications to § 411.370(e) to reflect this view.

We also appreciate the compliance burden on physicians and DHS entities subject to the physician self-referral law, as well as the significant consequences of noncompliance, and we acknowledge the desire for more timely guidance. Therefore, we are considering available means to provide general guidance and compliance advice outside of the advisory opinion process. Several commenters suggested that CMS issue more subregulatory guidance to provide greater clarity around the physician self-referral law and regulations. While subregulatory guidance must always be carefully constructed so as not to impose new obligations on regulated parties, CMS will explore opportunities to provide additional, appropriate guidance through subregulatory means. As we noted in the proposed rule, we respond to questions pertaining to the physician self-referral law through the CMS Physician Self-Referral Call Center email inbox, and frequently assists parties with identifying relevant guidance. The CMS Physician Self-Referral Call Center resource is free to the public, and inquiries may be sent to *1877CallCenter@cms.hhs.gov.* For additional information, *see https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Call-Center.html.* We also respond to frequently asked questions (FAQs) regarding the physician self-referral law from time to time. FAQs issued to date are available on our website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/FAQs.html.*

For these reasons, we are finalizing our proposed changes to § 411.370(b), with the modifications as described above. In response to commenters' desire for greater clarity around the types of requests that CMS will reject, we are also adding a new paragraph § 411.370(e)(1)(v) to clarify that CMS would decline to accept an advisory opinion request that involves a course of conduct that is not legally permissible for reasons other than section 1877 of the Act.

(ii) Acceptance of Requests

Current § 411.370(e) states that CMS does not accept an advisory opinion request or issue an advisory opinion if: (1) The request is not related to a named individual or entity; (2) CMS is aware that the same or substantially the same course of action is under investigation or is or has been the subject of a proceeding involving HHS or another governmental agency; or (3) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry. We proposed changes to this regulation. First, we proposed to add to the reasons that CMS will not accept an advisory opinion request or issue an advisory opinion. Specifically, we proposed that CMS will not accept an advisory opinion request or not issue an advisory opinion with respect to a request that does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information. We believe that this is important to the agency's ability to focus its resources on complete requests.

Second, we proposed to amend current § 411.370(e)(2), which states that CMS will not issue an advisory opinion if it is aware that the same, or substantially the same, course of action is under investigation or is or has been the subject of a proceeding involving HHS or other government entities. Although CMS consults with other HHS components and governmental agencies, including OIG and DOJ, on pending advisory opinion requests, we believe the current regulation is too restrictive, and unnecessarily limits CMS' flexibility to issue timely guidance to requestors engaged in or considering legitimate business arrangements. Therefore, we proposed to modify § 411.370(e)(2) to allow CMS more discretion to determine, in consultation with OIG and DOJ, whether acceptance of the advisory opinion request or issuance of the advisory opinion is appropriate. Specifically, we proposed at § 411.370(e)(2) that CMS may elect not to accept an advisory opinion request or issue an advisory opinion if, after consultation with OIG and DOJ, it determines that the course of action described in the request is substantially similar to conduct that is under investigation or the subject of a proceeding involving the Department or other law enforcement agencies, and that issuing an advisory opinion could interfere with the investigation or proceeding. We proposed to retain at renumbered § 411.370(e)(1)(iii) the restriction on accepting requests if CMS is aware that the same course of action is under investigation or is, or has been the subject of a proceeding involving the Department or another governmental agency. We also proposed to clarify that CMS would consult with OIG and DOJ regarding investigations or proceedings involving the same course of conduct described in an advisory opinion request.

We received public comments on these proposals. The following is a summary of the comments we received on the above proposals and our responses.

Comment: Commenters were generally supportive of the requirement that requests must contain a level of detail sufficient to permit CMS to issue an informed opinion, and that it would be appropriate to reject a request if the requestor did not timely respond to CMS' request for additional information. Several commenters opined that this safeguard will protect against inappropriate use of the advisory opinion process.

Response: We agree that this safeguard is necessary to protect the integrity of the advisory opinion process

and to ensure that CMS is focusing its resources on requests that provide sufficient detail to allow CMS to make an informed decision.

Comment: Several commenters agreed with CMS' current policy of rejecting advisory opinion requests where the same course of action described in the request is the subject of an investigation or proceeding.

Response: We are maintaining this current policy set forth at § 411.370(e)(1)(iii).

Comment: Commenters supported the proposed modifications to § 411.370(e) that would give CMS more flexibility with respect to requests involving conduct that is substantially similar to conduct that is under investigation or is the subject of a law enforcement proceeding. Several commenters stated that the current restriction at § 411.370(e)(2) unnecessarily limits CMS' ability to issue timely guidance to requestors engaged in or planning to enter into legitimate business arrangements. Several commenters urged CMS to reject such requests only where the issuance of an advisory opinion could have a direct effect on an investigation or proceeding. Several other commenters, however, suggested that CMS remove the restriction in its entirety, arguing that enforcement actions often involve lengthy investigations and litigation, and parties with substantially similar arrangements could be locked out of the advisory opinion process for long periods of time while these proceedings are ongoing. One commenter considered whether by maintaining the discretion to reject requests involving substantially similar conduct, CMS was unlikely to issue more advisory opinions than it currently issues.

Response: We believe it is important for CMS to retain discretion to reject an advisory opinion request where we determine, after consultation with OIG and DOJ, that issuance of an opinion would interfere with a pending investigation or proceeding. However, we recognize that the exercise of this discretion could result in parties to legitimate arrangements being locked out of the advisory opinion process for lengthy periods of time, and having to make business decisions without the certainty that an advisory opinion can provide. While we will strive to be judicious in our exercise of discretion, we may not be in a position to respond to every request in a timeframe that suits the requestor. In those instances, it is up to regulated parties to decide whether to pursue a particular course of conduct in the absence of an advisory opinion.

For the reasons stated above, we are finalizing our proposed changes to § 411.370(e), and, as described above in section b.(i), adding a new paragraph (e)(1)(v) to clarify that CMS would decline to accept an advisory opinion that involves a course of conduct that is not legally permissible for reasons other than section 1877 of the Act.

c. Timeline for Issuing an Advisory Opinion (§ 411.380)

Section 1877(g)(6) of the Act does not impose any deadlines by which the agency must respond to a physician self-referral law advisory opinion request, but it does require the Secretary to take into account OIG advisory opinion regulations under subsection (b)(5) of section 1128D of the Act. Section 1128D(b)(5)(B)(i) of the Act provides that the Secretary shall be required to issue an advisory opinion no later than 60 days after the request is received. In the 1998 CMS advisory opinions rule, we adopted a 90-day timeframe for most requests. In addition, for requests that we determined, in our discretion, involve complex legal issues or highly complicated fact patterns, we reserved the right to issue an advisory opinion within a reasonable timeframe. We created this timeframe based upon our estimates of the volume and complexity of expected requests, and based upon our then-current staffing situation.

We proposed to modify this time period and establish a 60-day timeframe for issuing advisory opinions. This period would begin on the date that CMS formally accepts a request for an advisory opinion. The 60 days would be tolled during any time periods in which the request is being revised or additional information compiled and presented by the requestor. We are adopting a 60-working day timeframe, and clarifying that day refers to a ''working day,'' where ''working days'' is defined as days excluding Saturdays, Sundays, and legal holidays.[111]

We also considered whether CMS should provide requestors with the option to request expedited review. We believe that a more efficient and expeditious process could give stakeholders more certainty and encourage innovative care delivery arrangements. We solicited comment on the changes to the timeframe, whether CMS in the final rule should include a provision on expedited review and, if so, the parameters for expedited review.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Commenters supported shortening the current 90-day timeframe to 60 days, although many commenters expressed skepticism that CMS would be able to meet such a deadline absent investment of additional resources or other process changes. One commenter requested more clarity as to when CMS ''formally accepts'' a request for an advisory opinion, thereby triggering the beginning of the 60-day timeframe.

Response: We are finalizing a 60-working day timeframe for issuance of advisory opinions, which will begin on the date that CMS formally accepts a request for review. We will formally accept a request once the agency determines that (a) the request and any supplemental submissions describe the arrangement at issue with a level of detail sufficient for CMS to issue the opinion, and (b) the grounds for rejection of a request listed at § 411.370(e) do not apply. We believe that the collection of user fees, a policy we proposed and are finalizing in this rule, will enable CMS to process advisory opinion requests in a timely fashion.

Under our current regulation, we reserve the ability to extend this default time period for requests that present complex legal issues of first impression, or highly complicated fact patterns, and to suspend the time period in the circumstances listed at § 411.380(c)(3). While we are maintaining this reservation of discretion, we appreciate commenters' views that requestors want some degree of assurance that their investment of time in the advisory opinion process will result in the timely issuance of an opinion.

Current regulations provide for a 15-working day review period that begins on the date CMS receives a request for an advisory opinion. Under the new timeframe, CMS will maintain this 15-working day review period. During this time, we will review the submission to make a preliminary[112] determination as to whether the submission describes the arrangement at issue with a level of detail sufficient for CMS to issue an opinion. For submissions clearly lacking in sufficient detail, we will notify the requestors of the deficiencies and request additional information. Once CMS makes a determination that the submission contains the necessary level

[111] ''Legal holidays'' include the days set aside by statute for observing New Year's Day, Martin Luther King Jr.'s Birthday, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans' Day, Thanksgiving Day, and Christmas Day; and any day declared a holiday by the President or Congress.

[112] CMS may or may not later need to request additional information during the 60-working day review timeframe.

of detail, we will consult with DOJ and OIG to determine whether grounds exist to reject the request. If CMS determines that it can accept the request for review, we will notify requestors that their submission is formally accepted.

Comment: Commenters supported the establishment of an expedited pathway for advisory opinion requests, and several noted that an expedited option would be particularly helpful with respect to transactions with an impending deadline. However, many of these same commenters also noted that the expedited pathway would only be meaningful if CMS had the resources to adhere to it.

Several commenters suggested that CMS establish a process for expedited review for relatively more straightforward requests that lend themselves to a ''yes'' or ''no'' answer, such as requests for CMS' opinion on whether an arrangement is ''indistinguishable in all material aspects'' from another arrangement upon which CMS has issued a favorable advisory opinion.

Response: We agree with commenters that an expedited review process would be appropriate for requests that seek a determination as to whether an arrangement is ''indistinguishable in all material aspects'' from another arrangement that has been reviewed and found to comply with the physician self-referral law. Based on these comments, we are finalizing modifications to § 411.380 to provide for expedited review for these types of requests only. Requestors would indicate in their advisory opinion requests that they are seeking expedited review. We will promptly make a determination on eligibility for expedited review, and communicate our decision to a requestor when notifying the requestor that CMS has formally accepted the request. The expedited review period of 30 working days would begin when CMS formally accepts the submission for review. We believe that the collection of user fees, a policy we proposed and are finalizing in this rule, will enable CMS to process advisory opinion requests in a timely fashion.

Comment: Several commenters suggested that in instances where CMS does not issue an advisory opinion within the relevant timeframe, the requestor should be deemed to have received a favorable advisory opinion and should be protected from any sanctions until such time as CMS formally issues an opinion.

Response: The physician self-referral law is a payment rule, and CMS is statutorily prohibited from making payment for DHS furnished pursuant to a prohibited referral where a financial arrangement exists and no exception applies. Therefore, we do not have the authority to ''deem'' an individual or entity in compliance with the physician self-referral law if such deeming would effectively override the statutory payment prohibition.

Comment: One commenter requested that CMS clarify the criteria it uses to determine whether a request involves ''complex legal issues or fact patterns.''

Response: We appreciate this comment and will consider providing guidance in the future as the agency gains more experience with the modified process.

As a result of the comments, we are finalizing our proposal to issue advisory opinions within 60 working days of the submission being formally accepted. We are also finalizing a 30-working day expedited review pathway for requests that only seek a determination that an arrangement is indistinguishable in all material respects to an arrangement that is the subject of a favorable advisory opinion.

d. Certification Requirement (§ 411.373)

In the 1998 CMS advisory opinions rule, we adopted a requirement identical to OIG's requirement that a requestor must certify to the truthfulness of its submissions, including its good faith intent to enter into proposed arrangements. CMS finalized regulations that require a requestor to make two certifications as part of its request for an advisory opinion. Under current § 411.373(a), the requestor must certify that, to the best of the requestor's knowledge, all of the information provided as part of the request is true and correct and constitutes a complete description of the facts regarding which an advisory opinion is being sought. If the request relates to a proposed arrangement, current § 411.373(b) states that the request must also include a certification that the requestor intends in good faith to enter into the arrangement described in the request. A requestor may make this certification contingent upon receiving a favorable advisory opinion from CMS or from both CMS and OIG. Under current § 411.372(b)(8), if the requestor is an individual, the individual must sign the certification; if the requestor is a corporation, the certification must be signed by the Chief Executive Officer, or a comparable officer; if the requestor is a partnership, the certification must be signed by a managing partner; and, if the requestor is a limited liability company, the certification must be signed by a managing member. We proposed to revise § 411.372(b)(8) to clarify that the certification must be signed by an officer that is authorized to act on behalf of the requestor, but that the signing officer need not be the Chief Executive Officer. We also considered whether it would be appropriate to eliminate the certification requirement in our regulations, given that section 1001 of Title 18 of the United States Code prohibits material false statements in matters within the jurisdiction of a federal agency. We solicited comment on whether the existing certification requirement creates undue burden for requestors, and whether the requirement is necessary given section 1001.

The following is a summary of the comments we received on our proposals and our response.

Comment: Commenters supported the modifications to § 411.372(b)(8) that would allow for any authorized officer of a corporation, in addition to the Chief Executive Officer of a corporation, to sign the certification statement. Most commenters thought the certification requirement was appropriate and not overly burdensome.

Response: Given these comments, we are finalizing the proposed changes in § 411.372(b)(8), and will maintain the certification requirement.

e. Fees for the Cost of Advisory Opinions (§ 411.375)

In the 1998 CMS advisory opinions rule, we established a fee that is charged to requestors to cover the actual costs incurred by CMS in responding to a request for an advisory opinion. Under current § 411.375, there is an initial fee of $250, and parties are responsible for any additional costs incurred that exceed the initial $250 payment. A requestor may designate a triggering dollar amount, and CMS will notify the requestor if CMS estimates that the costs of processing the request have reached or are likely to exceed the designated triggering amount. This fee structure was modeled after the OIG regulations that were in effect at that time.

Since CMS issued the 1998 CMS advisory opinions rule, OIG has updated its regulations to eliminate the initial fee, and instead charges requesting parties a consolidated final payment based on costs associated with preparing an opinion (73 FR 15936). In the proposed rule, we stated that we believe it is appropriate to adopt an hourly fee of $220 for the preparation of an advisory opinion. We said that we believe this amount reflects the costs incurred by the agency in processing an advisory opinion request. We also said that we were considering establishing an expedited pathway for requestors

that seek an advisory opinion within 30 days of the request, and charging $440 an hour to process the request, reflecting the extra resources necessary to produce an advisory opinion within the abbreviated timeframe. We requested comments on this approach. To ensure that obtaining an advisory opinion is affordable, and to prevent unfair surprises to requestors at the end of the process, we considered promulgating a cap on the amount of fees charged for an advisory opinion. We solicited comments on the amount of the cap. We also requested comments on whether CMS should eliminate the initial $250 fee.

The following is a summary of the comments we received on our proposals and our responses.

Comment: Many commenters were supportive of a user fee structure to enable the agency to handle a greater volume of advisory opinion requests and issue opinions in a shorter timeframe. Several commenters thought that the $220 hourly fee was reasonable, and one commenter noted that the $220 rate would ensure that only legitimate requestors are using the advisory opinion process.

Other commenters recommended alternatives to the proposed $220 hourly fee. For instance, commenters recommended adopting an hourly fee of $175 to align with OIG's charges, or adopting a flat ''filing fee.'' One commenter said that physicians should not pay more than the costs CMS incurs in responding to a request for an opinion, and that if CMS is going to adopt an hourly rate of $220, the agency should justify that amount.

One commenter stated that it would support user fees only to the extent those fees would enable the agency to issue advisory opinions on hypothetical facts, and cut the time the agency takes to issue advisory opinions. Another commenter stated that requestors should not be charged an hourly fee for work done by CMS after the expiration of the relevant time period.

Response: We agree with commenters that moving to an hourly rate structure will enable CMS to more efficiently and timely process requests for advisory opinions. Furthermore, the proposed rate of $220 is a reasonable rate given the experience and seniority of the staff and attorneys responding to advisory opinion requests. *See,* for example, USAO ATTORNEY'S FEES MATRIX—2015–2019, *available at https://www.justice.gov/usao-dc/file/796471/download* (reasonable hourly fee for an attorney with less than 2 years of experience practicing law exceeds $220 per hour for the 2018–2019 time period).

Comment: Commenters largely supported the establishment of a higher hourly rate for expedited review.

Response: Because we are finalizing an expedited review pathway only for certain types of requests that we expect to be more straightforward than other requests (that is, those that seek an opinion on whether an arrangement is ''indistinguishable in all material respects'' to another arrangement that is the subject of a favorable advisory opinion), we are not finalizing a $440 hourly rate at this time.

Comment: Several commenters suggested that the agency provide potential requestors with a cost estimate prior to the requestor incurring any costs. Many commenters supported the adoption of a cap, and several commenters recommended that CMS make special accommodations for small and solo practitioners such that they can afford to request advisory opinions. For example, several commenters that supported the imposition of hourly fees urged CMS to consider waiving fees for small groups of up to 15 clinicians, to ensure that smaller practices have access to the advisory opinion process. However, no commenter offered any suggestions on what an appropriate cap might be.

Response: We agree with commenters that in order for the advisory opinion process to be accessible, especially for rural providers and small and solo practitioners, the costs must be predictable and affordable. As we work on operationalizing these reforms to the advisory opinion process, we will consider whether it is feasible to provide requestors with a cost estimate for the review and issuance of an advisory opinion. We will also consider discounting, on a case-by-case basis, the $220 hourly rate for requestors with demonstrated limited financial resources, such as certain rural providers or small or solo practitioners, or, alternatively, capping the total charges for an advisory opinion.

Comment: Several commenters said they supported the elimination of the initial $250 fee, and that the elimination of the fee is appropriate if CMS were to finalize its hourly user fee structure.

Response: We agree and will modify § 411.375(a) to eliminate the initial $250 fee. Accordingly, we are also removing § 411.372(b)(9), which requires each advisory opinion request to include the initial $250 fee.

Comment: Several commenters suggested that we allow requestors to establish a triggering dollar amount, similar to the process used under OIG advisory opinion regulations.

Response: Our current regulations at § 411.375(c)(2) allow for requestors to designate a triggering dollar amount as a means of controlling the cost associated with the advisory opinion process. We are maintaining this provision, which will be redesignated as § 411.375(b)(2).

As a result of the comments, we are finalizing, with modification, our proposal on the timeline for issuance of an advisory opinion request, as well as certain modifications to clarify the process for formal acceptance of a submission.

f. Reliance on an Advisory Opinion (§ 411.387)

As we considered improvements to the advisory opinion process, we also considered regulatory changes to clarify current CMS policies and practices, and make our advisory opinions more useful compliance tools for stakeholders. Specifically, we solicited comment on proposals, described in more detail below, to remove some of the regulatory provisions limiting the universe of individuals and entities that can rely on an advisory opinion, and to add language expressing what we believe are permissible uses of an advisory opinion.

Section 1877(g)(6)(A) of the Act states that an advisory opinion shall be binding on the Secretary and on the party or parties requesting an opinion. Consistent with the policy adopted by OIG, CMS took the view that an advisory opinion may legally be relied upon only by the requestors. While section 1877 of the Act is silent on how third parties may use an advisory opinion, in regulation, CMS has precluded legal reliance on the opinion by non-requestor third parties. At the time, we stated that advisory opinions are capable of being misused by persons not a party to the transaction in question in order to inappropriately escape liability (63 FR 1648). While such a preclusion may be appropriate for purposes of an OIG advisory opinion on the application of a criminal statute, we stated in the proposed rule that we believed it may be unduly restrictive in the context of a strict liability payment rule that applies regardless of a party's intent.

We recognize that in practice, parties to an arrangement that is the subject of a favorable advisory opinion will rely on the opinion, even if the parties did not join in the request. If, for instance, CMS determines that an arrangement does not constitute a financial relationship because it satisfies all requirements of an applicable

exceptions to the physician self-referral law, that determination would necessarily apply equally to any individuals and entities that are parties to the specific arrangement, for example, the referring physician and the entity to which he or she refers patients for designated health services. Thus, even if the physician party to the arrangement was not a requestor of the advisory opinion, the physician party is entitled to rely on that advisory opinion. We proposed changes to § 411.387 to reflect this view. Specifically, we proposed at § 411.387(a) that an advisory opinion would be binding on the Secretary and that a favorable advisory opinion would preclude the imposition of sanctions under section 1877(g) of the Act with respect to the party or parties requesting the opinion and any individuals or entities that are parties to the specific arrangement with respect to which the advisory opinion is issued.

We proposed at § 411.387(b) that the Secretary will not pursue sanctions under section 1877(g) of the Act against any individuals or entities that are parties to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion. All facts relied on and influencing a legal conclusion in an issued favorable advisory opinion are material; deviation from that set of facts would result in a party not being able to claim the protection proposed in § 411.387(b). A favorable advisory opinion with respect to one arrangement would not legally preclude CMS from pursuing violations against parties to a different arrangement. In practice, the Secretary will not use CMS enforcement resources for purposes of imposing sanctions under section 1877(g) of the Act to investigate the actions of parties to an arrangement that CMS believes is materially indistinguishable from an arrangement that has received a favorable advisory opinion. As discussed above, such a determination would not preclude a finding by DOJ or OIG that the arrangement violates a law other than the physician self-referral law, including but not limited to the anti-kickback statute. If parties to an arrangement are uncertain as to whether CMS would view it as materially indistinguishable from an arrangement that has received a favorable advisory opinion, then those parties can submit an advisory opinion request. We solicited comment on this approach.

Finally, we also proposed at § 411.387(c) to recognize that individuals and entities may reasonably rely on an advisory opinion as non-binding guidance that illustrates the application of the physician self-referral law and regulations to specific facts and circumstances. We acknowledge that stakeholders already look to advisory opinions issued by CMS to inform their decision-making, and these changes will make clear that CMS acknowledges that such reliance is permissible and reasonable. We requested comments on all aspects of these proposals.

The following is a summary of the comments we received on our proposals and our responses.

Comment: Commenters were supportive of our proposals to remove the restrictions on the individuals and entities that can rely on an advisory opinion. These commenters stated that these modifications will help reduce confusion about compliance with the physician self-referral law, enhance utilization of the advisory opinion process, and maximize the ability of health care entities to innovate and form beneficial business arrangements.

Response: We appreciate the support for these proposals, which we agree will remove unnecessary restrictions on how regulated individuals and entities can use advisory opinions to guide their decisions and aid in compliance activities.

Comment: Several commenters encouraged CMS to continue publishing advisory opinions on its website, with identifiers and any privileged, confidential or proprietary information redacted. At least one commenter suggested that CMS publish an annual reporting summarizing the number of advisory opinions issued and statistics such as the number of advisory opinion requests submitted, the number withdrawn, and information on compliance with regulatory timelines.

Response: We will continue to publish advisory opinions on our website as well as redact information that identifies the requestors and other specific parties. We encourage potential requestors to review the Department's regulations at 45 CFR part 5, which explain how to identify and protect confidential commercial information. We appreciate the suggestion regarding annual statistics on the number of advisory opinion requests received each year, and the disposition of those requests. We are not making any regulatory changes to address this comment, but we will consider publishing such statistics for the next calendar year.

Comment: A few commenters pointed out that accountable care organization (ACO) arrangements can take on a variety of forms, so any single ACO arrangement may be substantially similar, but not identical to, another ACO arrangement that has been the subject of a favorable advisory opinion. These commenters urged CMS to consider how we might adopt a more flexible approach to enable parties to an ACO to rely on an advisory opinion issued to a substantially similar ACO.

Response: Under the regulations we are adopting in this final rule, at § 411.387(c), ACO participants could rely on an advisory opinion as non-binding guidance, even if their ACO arrangement is substantially similar to but not the same as the arrangement that is the subject of the advisory opinion. If the ACO's participants wanted more certainty as to whether CMS would view the factual differences as material, the ACO participants—subject to the physician self-referral law—could request their own advisory opinion through the expedited pathway. If we determined that the arrangement was materially distinct from others that have been the subject of favorable advisory opinions, the requestors would have the option of requesting a new advisory opinion through the normal process.

Comment: Several commenters suggested that CMS should make clear in its regulations that reasonable reliance on an advisory opinion is sufficient to defeat a claim under the False Claims Act that a physician or entity knowingly submitted a false claim as a result of a violation of the physician self-referral law.

Response: We are not authorized to and do not enforce the False Claims Act, and our authority to issue regulations governing the advisory opinion process does not give us the authority to issue regulations interpreting elements of the False Claims Act. We note that a favorable advisory opinion means that CMS has determined that specific referrals for designated health services referrals under the arrangement in question are not prohibited under section 1877 of the Act (as limited to the individuals or entities requesting the opinion and any individuals or entities that are parties to the specific arrangement with respect to which the favorable advisory opinion is issued so long as the specific arrangement as implemented does not deviate from the material facts upon which the advisory opinion is based).

Comment: A few commenters requested that individuals who join arrangements that are the subject of issued advisory opinions have those advisory opinions apply to them retrospectively.

Response: We appreciate this suggestion, however the applicability of an advisory opinion to an individual

joining the arrangement that is the subject of the issued advisory opinion would be a fact-specific determination.

As a result of the comments, we are finalizing the proposed modifications to § 411.387.

g. Rescission (§ 411.382)

Under current § 411.382, CMS may rescind or revoke an advisory opinion after it is issued if CMS determines that it is in the public interest to do so. To date, CMS has not rescinded an advisory opinion. At the time we finalized this regulation, which is modeled on OIG's rescission authority regulation, we sought comment on whether this approach reasonably balanced the government's need to ensure that advisory opinions are legally correct and the requestor's interest in finality (63 FR 1653). We again requested comment on this issue. Specifically, we solicited comments on whether CMS should retain a more limited right to rescind an advisory opinion; that is, CMS could rescind an advisory opinion only when there is a material regulatory change that impacts the conclusions reached, or when a party has received a negative advisory opinion and wishes to have the agency reconsider the request in light of new facts or law.

The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported limiting the grounds upon which CMS would rescind an advisory opinion. Specifically, most commenters agreed that rescission would be appropriate when there is a material regulatory change that affects the conclusions reached in an issued advisory opinion, or when a party that has received a negative advisory opinion wishes to have the agency reconsider the request in light of new facts or law.

Response: We appreciate the feedback on the advisory opinion rescission policy, and agree that the proposed regulatory modification is warranted to provide regulated individuals and entities with greater clarity regarding when CMS believes a rescission may be appropriate. We are therefore modifying § 411.382(a) to provide that CMS may rescind an advisory opinion if it determines that there is good cause to rescind the opinion. In addition, we are modifying § 411.382(a) to provide that ''good cause'' exists when (i) there is a material change in the law that affects the conclusions reached in an opinion; or (ii) a party that has received a negative advisory opinion seeks reconsideration based on new facts or law.

Comment: Many commenters encouraged CMS to provide adequate notice to affected parties and provide adequate time for parties to wind down existing arrangements. Several commenters suggested that CMS allow for a wind-down period. These commenters differed on the appropriate length of a wind-down period. Suggestions included 90 days, 120–180 days, and 3–5 years. Several commenters also suggested that CMS provide for a reasonable period of public notice of no less than 30 days, given the expectation that non-requesting parties will rely on issued advisory opinions. Commenters also requested assurance that CMS would not apply an advisory opinion rescission or revocation in a retrospective manner.

Response: Our current regulations at § 411.382 already provide flexibility for CMS to allow for a reasonable ''wind down'' period to discontinue activities that are the subject of a rescinded advisory opinion. Because every arrangement is unique, and because the allowance of a wind down period amounts to an exercise of agency enforcement discretion, we do not believe it is appropriate for us to establish a minimum wind-down period in regulations. In the event that CMS does, in the future, rescind an advisory opinion, we will work with affected parties to determine a reasonable and appropriate wind down period.

We appreciate commenters' suggestions regarding public notice of a potential rescission. We agree that providing public notice is appropriate given our expectation that non-requesting parties may be relying on an issued advisory opinion to guide their decisions and conduct. We are therefore finalizing an amendment to § 411.382 that provides for advance notice to both the requestor and the public.

As a result of the comments, we are finalizing changes to § 411.382 that will codify the limited instances that a rescission would be appropriate.

h. Other Modifications to Procedural Requirements

We proposed minor modifications to § 411.372 to improve readability and clarity. We also proposed to eliminate the reference to the provision of stock certificates as part of the advisory opinion request submission, as these are typically electronic and may not necessarily list the name of the owner. We requested comments on these and other updates to the procedure for submitting an advisory opinion request that will improve the efficiency of the review process.

Comment: At least one commenter stated that our proposed modifications to the advisory opinion process did not address what they view as a disconnect between the OIG's enforcement of the anti-kickback statute and CMS' enforcement of the physician self-referral law. This commenter stated that the lack of a process to obtain joint agency advisory opinions on specific fact scenarios limits the ability of stakeholders to understand how the two agencies may interpret the two laws differently when reviewing the same factual situation. The commenter said it would be optimal if there were a joint process to obtain both agencies' input on hypothetical arrangements or questions of general applicability. They also said such a joint process would further the Administration's goal of reducing regulatory burden on providers.

Response: We appreciate this comment and recognize that the physician self-referral advisory opinion process, standing alone, cannot give a regulated party certainty that its course of conduct is protected from scrutiny under the anti-kickback statute, even if that party has received a favorable advisory opinion from CMS regarding the arrangement in question. Currently, the timelines for issuing advisory opinions differ under the respective CMS and OIG regulations. Therefore, establishing a joint process is not feasible. However, we will consider how we could achieve greater alignment with the OIG process in the future.

Comment: One commenter suggested that the agency explore whether it has legislative authority to issue opinions that offer protection for arrangements even if they may not squarely fit within an exception, but pose no significant risk of harm.

Response: Due to the nature of the physician self-referral law, we do not have the legislative authority to protect referrals of designated health services that are furnished in violation of the law, even if it is the belief of the parties that the referrals are made pursuant to an arrangement that does not pose a significant risk of harm. Section 1877(g)(1) of the Act states that ''no payment may be made'' for prohibited referrals, and section 1877(g)(6) of the Act limits the scope of our advisory opinion authority to questions of whether or not a referral related to designated health services is prohibited. The commenter's request would require legislative change.

K. CY 2020 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the final rule sets forth changes to the Quality Payment Program starting January 1, 2020, except as otherwise noted for specific provisions. The 2020 performance period of the Quality Payment Program will build upon the foundation that has been established in the first 3 years of the program, which provides a trajectory for clinicians moving to performance-based payments, and will gradually prepare clinicians for the 2022 MIPS performance period of the program and the 2024 MIPS payment year. Participation in both tracks of the Quality Payment Program—Advanced Alternative Payment Models (APMs) and Merit-based Incentive Payment System (MIPS)—has increased from 2017 to 2018.[113] The number of QPs—Qualifying APM Participations—nearly doubled from 2017 to 2018, from 99,076 to 183,306 clinicians. In MIPS, 98 percent of eligible clinicians participated in 2018, up from 95 percent in 2017. As the Quality Payment Program continues to mature, CMS recognizes additional long-term improvements will need to occur. We have taken stakeholder input into consideration to ensure that we continue to implement the Quality Payment Program as required while smoothing the transition where possible and offering targeted educational resources for program participants. For example, in an effort to get broad feedback on our MIPS Value Pathways (MVPs) participation framework we held a public webinar specifically focused on the topic, conducted 7 listening sessions with various stakeholder groups throughout the proposed rule comment period, and engaged with clinicians and others through several other public forums. We plan to continue engaging with clinicians and other stakeholders as we move forward developing the MVPs.

While we continue efforts to strengthen the Quality Payment Program, we remain interested in clinician participation and engagement in the program, particularly as initial MVPs are developed for the 2021 MIPS performance period. We have been given flexibility in establishing the cost performance category weight and performance threshold in the early years of the Quality Payment Program. The Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018) extended the flexibility and transition years within the Quality Payment Program. Beginning with the 2024 MIPS payment year (2022 performance period), as required by law, the cost performance category under MIPS will be weighted at 30 percent and the performance threshold will be set at the mean or median of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. The provisions of this rule are intended to recognize our reduced flexibility beginning with the 2024 MIPS payment year and continue to put clinicians in a position to make the transition as required by statute.

b. Summary of Major Provisions

(1) MIPS Value Pathways

We are committed to the transformation of MIPS, which will allow for: More streamlined and cohesive reporting; enhanced and timely feedback; and the creation of MVPs of integrated measures and activities that are meaningful to all clinicians from specialists to primary care clinicians and to patients. The new MVPs will remove barriers to APM participation and promote value by focusing on quality and cost measure and improvement activities built on foundational global or population quality measures calculated from claims-based quality data and promoting interoperability concepts.

In the CY 2020 PFS proposed rule (84 FR 40735), we proposed to apply a new MVP framework beginning with the 2021 MIPS performance period/2023 MIPS payment year to simplify MIPS, improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians. As discussed in section III.K.3.a.(2) of this final rule, we are finalizing a modified proposal to define MVPs at § 414.1305 as a subset of measures and activities established through rulemaking.

Additionally, we will work with stakeholders to develop MVPs as a cohesive and meaningful participation experience for clinicians with an aligned set of measures and activities that are more relevant to a clinician's scope of practice, while further reducing reporting burden and easing the transition to APMs. We refer readers to the CY 2020 PFS proposed rule (84 FR 40732 through 40745) for more information on the MVP framework.

(2) Other Major MIPS Provisions

In addition to the MVP framework, we are finalizing two significant proposals for the 2020 MIPS performance period:

- As discussed in section III.K.3.g.(3) of this final rule, we are finalizing the proposal to strengthen the Qualified Clinical Data Registry (QCDR) measure standards for MIPS to require measure testing, harmonization, and clinician feedback to improve the quality of QCDR measures available for clinician reporting. These policies relate to CY 2020 and CY 2021 for QCDRs.
- As discussed in section III.K.3.c.(2)(b)(iii) of this final rule, we are finalizing the proposed episode-based measures in the cost performance category to more accurately reflect the cost of care that specialists provide. Further, we are also finalizing the revised total per capita cost and the Medicare Spending Per Beneficiary (MSPB) measures.

After consideration of public comments, we are not finalizing two significant proposals:

- As discussed in section III.K.3.c.(2)(a) of this final rule, we are not finalizing our proposal to weight the cost performance category at 20 percent for the 2022 MIPS payment year. Instead, we are continuing to weight the cost performance category at 15 percent in light of concerns noted regarding more detailed and actionable performance feedback. Hence, we are also continuing to weight the quality performance category, discussed in section III.K.3.c.(1)(b) of this final rule, at 45 percent. However, we will revisit increasing the weight of the cost performance category in next year's rulemaking to ensure clinicians are prepared for the significant increase in category weight by the 2024 MIPS payment year.
- As discussed in section III.K.3.e.(3) of this final rule, we are not finalizing our proposal to set the additional performance threshold at 80 points for the 2022 MIPS payment year and instead are finalizing the additional performance threshold at 85 points for the 2022 MIPS payment year. We are also finalizing the additional performance threshold at 85 points for the 2023 MIPS payment year.

(3) Major APM Provisions

(a) Aligned Other Payer Medical Home Models

We are finalizing the proposal to add the defined term, Aligned Other Payer Medical Home Model, to § 414.1305. The definition of Aligned Other Payer Medical Home Model includes the same characteristics as the definitions of

[113] Quality Payment Program (QPP) Participation in 2018: Results at a Glance *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/586/2018%20QPP%20Participation%20Results%20Infographic.pdf.*

Medical Home Model and Medicaid Medical Home Model, but it applies to other payer payment arrangements. We believe that structuring this definition in this manner is appropriate because we recognize that other payers could have payment arrangements that may be appropriately considered medical home models under the All-Payer Combination Option.

Neither the current Medical Home Model financial risk and nominal amount standards nor the Medicaid Medical Home Model financial risk and nominal amount standards apply to other payer payment arrangements. Consistent with our decision to finalize our proposal to define the term Aligned Other Payer Medical Home Model, we are finalizing our proposal to amend § 414.1420(d)(2), (d)(4), and (d)(8) to apply the same Medicaid Medical Home Model financial risk and nominal amount standards, including the 50 eligible clinician limit, to Aligned Other Payer Medical Home Models.

(b) Marginal Risk for Other Payer Advanced APMs

We are finalizing our proposal to modify our definition of marginal risk when determining whether a payment arrangement is an Other Payer Advanced APM. We proposed that, in the event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, we will compare the average marginal risk rate across all possible levels of actual expenditures to the marginal risk rate specified in the Other Payer Advance APM financial risk criterion, with exceptions for large losses and small losses, as described in § 414.1420(d). When considering average marginal risk in the context of total risk, we believe that certain risk arrangements can create meaningful and significant risk-based incentives for performance and at the same time ensure that the payment arrangement has strong financial risk components.

(c) Estimated APM Incentive Payments and MIPS Payment Adjustments

As we discuss in section VII.F.10.a. of this final rule, for the 2022 payment year and based on estimated Advanced APM participation during the 2020 QP Performance Period, we estimate that between 210,000 and 270,000 clinicians will become Qualifying APM Participants (QPs). Eligible clinicians who are QPs for the 2022 payment year are excluded from the MIPS reporting requirements and payment adjustment and will receive a lump sum APM Incentive Payment equal to 5 percent of their aggregate payment amounts for covered professional services for the year prior to the payment year. We estimate that the total lump sum APM Incentive Payments will be approximately $535–685 million for the 2022 Quality Payment Program payment year.

We estimate that there will be approximately 879,966 MIPS eligible clinicians for the 2020 MIPS performance period in section VII.F.10.b.(1)(b) of this final rule. The final number will depend on several factors, including the number of eligible clinicians excluded from MIPS based on their status as QPs or Partial QPs, the number that report as groups, and the number that elect to opt into MIPS in accordance with § 414.1310(b)(1)(ii). In the 2022 MIPS payment year, MIPS payment adjustments, which only apply to payments for covered professional services furnished by a MIPS eligible clinician, will be applied based on a MIPS eligible clinician's performance on specified measures and activities within four integrated performance categories. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments ($433 million) and positive MIPS payment adjustments ($433 million) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Up to an additional $500 million is also available for the 2022 MIPS payment year for additional positive MIPS payment adjustments for exceptional performance for MIPS eligible clinicians whose final score meets or exceeds the additional performance threshold of 85 points that we are finalizing in section III.K.3.e.(3) of this final rule. However, the distribution will change based on the final population of MIPS eligible clinicians for the 2022 MIPS payment year and the distribution of final scores under the program.

2. Definitions

At § 414.1305, we are finalizing definitions of the following terms:

- Aligned Other Payer Medical Home Model.
- Hospital-based MIPS eligible clinician.
- MIPS Value Pathway.

We are also finalizing revisions to the following definition at § 414.1305:

- Rural area.

These terms and definitions are discussed in detail in relevant sections of this final rule.

3. MIPS Program Details

a. Transforming MIPS: MIPS Value Pathways

(1) Overview

In the CY 2020 PFS proposed rule, we proposed an MVP definition that would prepare us to apply a new MVP framework beginning with the 2021 MIPS performance period. This MVP framework would simplify MIPS, improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians. We refer readers to the CY 2020 PFS proposed rule (84 FR 40732 through 40745) for more information on the MVP framework and the proposed MVP definition.

(2) Implementing MVPs

In the CY 2020 PFS proposed rule (84 FR 40735), we described the MVP framework and proposed to define a MIPS Value Pathway at § 414.1305 as a subset of measures and activities specified by CMS. We noted that MVPs may include, but will not be limited to, administrative claims-based population health, care coordination, patient-reported (which may include patient reported outcomes, or patient experience and satisfaction measures), and/or specialty/condition specific measures. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the MVP framework and proposed definition of an MVP because this could potentially reduce the complexity of the MIPS program and clinician burden. Many commenters agreed with the intent of the MVP framework to simplify MIPS, reduce burden, make the program more meaningful for clinicians and reduce barriers to movement into APMs.

Response: We thank commenters for their support.

Comment: Several commenters stated that the MVP framework was a positive first step and they would like to see further burden reduction beyond clinician measure selection burden, including the elimination of the siloed requirements and scoring approaches for each of the four performance categories. Several commenters suggested streamlined reporting or automatic credit for Promoting Interoperability and Improvement Activities performance categories. Several commenters recommended that participation in a specialty accreditation program earn credit as an improvement activity. Several commenters suggested the use of measures that satisfy the requirements of multiple performance

categories in MVPs. A few commenters provided an example of linking measures: One example was to allow a clinician to report the quality measure, Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%), and the improvement activity, Glycemic Screening Services (IA_PM_19) to receive credit for a quality measure and improvement activity.

Response: We intend to develop MVPs in collaboration with stakeholders that align with guiding principles that include simplification and clinician burden reduction. We intend to work with stakeholders to develop MVPs that account for variation in specialty, size, and composition of clinician practices. We also intend that MVPs would allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a patient population, a specialty or a medical condition, reducing the siloed nature of the current MIPS participation experience. We believe it is important to develop MVPs in unison with stakeholders to create low burden, meaningful MVPs that move clinicians along the value continuum and facilitate movement into APMs. Experience with MVPs that measure quality of care and patient experience of care, cost, continuous practice improvement, and effective management and transfers of health information will help to reduce barriers to APM participation. We would like to work with stakeholders to identify specialty accreditation programs, such as the American College of Surgeons' Commission on Cancer Accreditation program that demonstrate a commitment to quality improvement and alignment with MIPS quality measures. We intend to develop MVPs to connect measures across performance categories as indicated by the commenter's diabetes example above. We note that the MIPS statute requires the use of four performance categories now called Quality, Cost, Improvement Activities, and Promoting Interoperability in determining the MIPS composite performance score. While each performance category has its own requirements and associated list of measures or activities, it is possible that a single measure or activity may meet the respective criteria for inclusion in more than one performance category; however, we do not currently have any multicategory MIPS or QCDR measures available. We would be interested in working with stakeholders to pair the improvement activities and quality and cost measures, while leveraging foundational global or population health measures and Promoting Interoperability measures that would constitute an MVP. We are interested in the potential use of measures that could satisfy more than one of the four MIPS performance categories within our statutory constraints and welcome additional stakeholder engagement related to how to best structure and develop MVPs that entail low clinician burden. Feedback and suggestions will be considered as we undertake further rulemaking in future years.

Comment: Many commenters indicated conditional support for the MVP framework, with concerns about the timeline and transition to MVPs in CY 2021. Many commenters requested a longer and more gradual timeline for MVP implementation. Several commenters suggested delaying MVP implementation by 1 year to CY 2022, while several others suggested a delay of a few years, with a few specifying a 2-year delay. Many commenters stated concerns that implementation in the 2021 MIPS performance period will not allow enough time to develop MVPs for all specialists, and several commenters indicated concerns about the time needed to educate clinicians on the use of MVPs. Many commenters supported MVPs as a voluntary reporting option in addition to the currently available options for MIPS participation. Several commenters recommended that MVPs be optional during a transition period. Several commenters supported the proposed MVP definition provided that MVPs are implemented as a voluntary gradual or multiyear pilot, allowing development and clinician MVP education time. A few commenters indicated that there is a need for stability in the Quality Payment Program and urged caution with implementation of the MVP framework.

Response: We have not made any proposals regarding whether participation in MVPs will be mandatory or optional. We appreciate that we need to work diligently with stakeholders to develop and propose policies regarding many aspects of implementation of MVPs in the 2021 MIPS performance period, including the extent of first year implementation or the feasibility of an initial pilot. Feedback and suggestions will be considered as we undertake further rulemaking in future years.

Comment: A few commenters did not support implementing the MVP framework stating that the MVPs would create too much change and clinician confusion with a few commenters stating that MVPs would not serve the needs of their specialty (for example, dermatology, nurse practitioners, physician assistants, occupational therapy, audiology, speech language pathology), indicating insufficient numbers of quality measures for the specialty. A few commenters stated that certain clinician types, for example, nurse practitioners, have only a single Medicare specialty designation but practice in diverse specialty areas and that a limited number of potentially assigned MVPs may leave some clinicians out. A few commenters indicated that specialty clinicians would need either multiple MVPs or an MVP with a wide variety of measures and activities, because of the range of services provided by a specialty. For example, surgeons provide a wide range of procedures from neurosurgery to spine care. A few commenters indicated that clinicians new to MIPS reporting should have a delayed MVP timeline. A few commenters stated that the MVPs, as described, would not be able to meet the stated goals because MVPs may reduce the burden of measure selection, but will not reduce the overall burden of participating in MIPS, which the commenters indicated would require removing separate requirements for scoring and reporting for each of the performance categories. Many commenters did not support transitioning towards MVPs because this would reduce clinician choice in the selection of measures and activities; and may rely on measures and activities, including population health measures, viewed as not relevant to the clinician's clinical practice.

Response: We believe achieving the goals of the MVP framework are worthwhile and understand the need to introduce change that is balanced against the burden required for clinicians to change workflows and participate in the program. A notable change for MIPS eligible clinicians with MVPs is that they would no longer select quality measures or improvement activities from a single inventory. Instead, measures and activities in an MVP would be connected around a clinician specialty or a clinical condition. We welcome ideas from stakeholders for developing MVPs that provide further burden reduction to clinicians. We acknowledge that a single MVP may not fit the needs of all clinician types and all clinicians in the specialty and would like to work with stakeholders to determine, to the extent possible, the number of MVPs needed for specialists and which measures and activities should be included. We would like to engage with clinicians in the field and their societies to develop applicable MVPs and foundational

population health administrative claims measures that are low burden and meaningful. We believe that holding all clinicians accountable for the same population health measures will align incentives, encourage coordination between clinicians and promote meaningful progress on measures. We seek ongoing engagement with stakeholders to identify population health measures that will drive collaborative, high-quality and timely care. We believe that ongoing engagement with stakeholders will lead to improved clinicians' experience with the Quality Payment Program and drive meaningful change in the delivery system. We will consider this feedback on how to best transition to MVPs and how to optimally include MVPs that meet the needs of all clinician specialties.

Comment: Several commenters requested additional information about how equity would be maintained between clinicians reporting on MVPs and those using the currently available MIPS participation options, as well as between clinicians reporting on different MVPs, indicating a concern that one MIPS participation option or MVP should not be 'easier' than others.

Response: We agree that equity is critical to MVP implementation and requested feedback on approaches we should take to create equity across MVPs and across clinician types (84 FR 40742). We intend to work with stakeholders to determine approaches to maintain equity between MVP and the MIPS participation option, as well as clinicians reporting on different MVPs. This feedback will inform our process development as we further develop our MVP framework and unique MVPs and undertake future rulemaking.

Comment: Many commenters expressed concerns related to the population health claims-based performance measures that would be selected for use in MVPs. Many commenters did not support the use of population health claims-based measures in MVPs because of reliability, validity, attribution, lack of risk adjustment, actionability concerns, and/or unintended consequences concerns. Several commenters supported foundational use of population health claims-based measures, with a few commenters supporting use of administrative measures that are consistent with Advanced APM measures stating that administrative measures can assess quality across time and the delivery system without clinician reporting and can be applied to various clinician types including specialties.

Response: We intend to work in close partnership with stakeholders to identify measures and activities to include in MVPs. Our vision for MVPs is to connect the four performance categories while using a foundational layer of population health claims-based measures and interoperability on which to build quality, cost and improvement activity linkages. Please refer to the on line MVP graphic (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/587/MIPS%20Value%20Pathways%20Diagrams.zip*) that provides an overview of our vision for the MIPS future state. Implementation of a foundational population health core measure set using administrative claims-based quality measures that can be broadly applied to communities or populations can result in MVP measure tracks that provide more uniformity in the program's measures, reduce clinician reporting burden, allow focus on important public health priorities, increase the value of MIPS performance data, and reduce barriers to APM participation. Additionally, we intend to examine these concerns regarding population health measure reliability, validity, attribution and risk adjustment and the technical challenges and address them to the extent feasible by working with the measure stewards and clinician experts. We believe that interoperability is also a foundational element that would apply to all clinicians, regardless of MVP, for whom the Promoting Interoperability performance category is required. We envision an initial uniform set of Promoting Interoperability measures in each MVP and will consider customizing MVP Promoting Interoperability measures in future years. We believe that eligible clinicians could benefit from more targeted approaches that assess the meaningful use of health IT in alignment with clinically relevant MVPs. The integration of population health measures and Promoting Interoperability measures into MVPs provides a degree of standardization across all clinician types and promotes an infrastructure on which to assess and improve value-based care. Measure feedback and suggestions will be considered as we undertake further rulemaking in future years.

Comment: Many commenters indicated that a critical element of specifying the measures and activities within an MVP will be stakeholder engagement. Many commenters urged us to work in tandem with clinicians and specialty societies to develop MVPs. A few other commenters suggested that specialty societies should develop MVPs. A few commenters urged us to work with multi-stakeholder consensus-based organizations such as the Core Quality Measures Collaborative and to utilize existing specialty measure set development approaches to identify a list of measures for each MVP. A few commenters suggested that we allow stakeholders to comment on the detailed methodologies of a future MVP design and implementation plan as they become more fully developed.

Response: We appreciate the commenters' recommendations on how the measures and activities should be specified in the MVPs and for articulating the critical importance of stakeholder engagement in MVP development. In recognition of our intention to specify MVPs with stakeholder input to the extent possible, we are modifying the proposed definition of MVP at § 414.1305, by replacing the words, ''as specified by CMS'' with ''established through rulemaking''.

After consideration of the comments, we are finalizing a modification of our proposal. Specifically, we are finalizing at § 414.1305 that MIPS Value Pathway means a subset of measures and activities established through rulemaking.

(3) Requests for Feedback on MVPs

In the CY 2020 PFS proposed rule (84 FR 40739 through 40745), we requested public comments regarding several issues involving the MVPs. We received 2,100 comments related to implementation of MVPs. While we are not summarizing and responding to comments we received in this final rule, we thank the commenters for their responses and may take them into account as we develop future policies for the MVPs. We also are interested in engaging with stakeholders on additional ways to reduce burden in the MIPS program, in addition to what we have solicited comment on for MVPs. For example, in the context of MVPs, we are interested in solutions to reduce burden across all 4 MIPS categories such as use of standards such as Fast Healthcare Interoperability Resources (FHIR), number of measures across categories, reporting timeframes and data submission methods. We intend to continue a dialogue with stakeholders on these important MVP topics and may consider convening public forum listening sessions, webinars, and office hours or using additional opportunities such as the pre-rulemaking process to further understand what is important to clinicians, patients, and stakeholders

and obtain further input as we develop MVPs.

b. Group Reporting

For previous discussions of the policies for group reporting, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77070 through 77073) and the CY 2018 Quality Payment Program final rule (82 FR 53592 through 53593). In addition, for previous discussions of the policies for group reporting related to the Promoting Interoperability performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77214 through 77216) and the CY 2018 Quality Payment Program final rule (82 FR 53687).

As discussed in the CY 2020 PFS proposed rule (84 FR 40745), it has come to our attention that the regulation text regarding group reporting at § 414.1310(e)(3) through (5) contains duplicative language. Specifically, it is duplicative of the regulation text at § 414.1310(e)(2)(ii) through (iv). To avoid redundancy and potential confusion, we proposed to remove § 414.1310(e)(3) through (5). In addition, we have noticed that previously established policies for group reporting with regard to the Promoting Interoperability performance category (81 FR 77214 through 77216, 82 FR 53687) are not reflected in the regulation text for group reporting at §§ 414.1310(e)(2)(ii) and for virtual groups at § 414.1315(d)(2). In the CY 2017 Quality Payment Program final rule (81 FR 77215), we stated that to report as a group for the Promoting Interoperability performance category, the group will need to aggregate data for all of the individual MIPS eligible clinicians within the group for whom they have data in CEHRT. In an effort to more clearly and concisely capture our existing policy for the Promoting Interoperability performance category, we proposed to revise §§ 414.1310(e)(2)(ii) and 414.1315(d)(2). Specifically, we proposed to revise § 414.1310(e)(2)(ii) to state that individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT.

Similarly, we proposed to revise § 414.1315(d)(2) to state that solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the clarification of the regulation text on group reporting and the need to aggregate the performance data across the group's TIN.

Response: We appreciate the commenters' support.

Comment: One commenter sought clarification regarding whether a virtual group needs to aggregate Promoting Interoperability performance data through reports or if the aggregation can be done manually prior to attestation. A few commenters sought clarification on whether there is a percentage of MIPS eligible clinicians that must have CEHRT for the group to attest due to their belief that the language as stated could be used to allow a group to only implement 2015 CEHRT for certain clinicians instead of across the entire TIN.

Response: If all the clinicians in a group or virtual group share the same CEHRT, the reports from CEHRT will include all of their data. However, if they are using different CEHRT, they will have to run the reports for each iteration of CEHRT and manually perform the aggregation. We did not establish a threshold for the percentage of MIPS eligible clinicians that must be using CEHRT in order for the group to report for MIPS as a group. The group must submit data for all of the MIPS eligible clinicians in the group for whom the group has data in CEHRT.

After consideration of the comments, we are finalizing these proposals, as proposed. Specifically, we are finalizing the proposals to: (1) Remove § 414.1310(e)(3) through (5); (2) revise § 414.1310(e)(2)(ii) to state that individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT; and (3) revise § 414.1315(d)(2) to state that solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.

c. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

We refer readers to § 414.1330 through § 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

In the CY 2020 PFS proposed rule (84 FR 40745 through 40746), we:

- Proposed to weigh the quality performance category at 40 percent for the 2022 MIPS payment year, 35 percent for the 2023 MIPS payment year, 30 percent for the 2024 MIPS payment year as described in § 414.1330(b)(4), (5), and (6); the associated increases to the weight of the cost performance category are discussed in section III.K.3.c. (2) of this final rule;
- Solicited comment on adding narratives to the CAHPS for MIPS survey and on whether the survey should collect data at the individual eligible clinician level;
- Proposed to increase of the data completeness criteria to 70 percent for the 2022 MIPS payment year as described in § 414.1340(b)(3);
- Proposed to require MIPS quality measure stewards to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible;
- Solicited comment as to whether we should consider realigning the MIPS quality measure update cycle with that of the eCQM annual update process;
- Proposed changes to the MIPS quality measure set as described in Appendix 1 of this proposed rule, including: Substantive changes to existing measures, addition of new measures, removal of existing measures, and updates to specialty sets;
- Solicited comment on whether we should increase the data completeness threshold for extremely topped out quality measures that are retained in the program due to limited availability of measures for a specific specialty and potential alternative solutions in addressing extremely topped out measures;
- Proposed to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in

the program for 2 consecutive CY performance periods;

- Proposed to remove quality measures from the program in instances where the measure steward or owner refuses to enter into a user agreement with CMS; and
- Requested information on a Potential Opioid Overuse Measure.

(b) Contribution to Final Score

Under § 414.1330(b)(2), we state that performance in the quality performance category will comprise 50 percent of a MIPS eligible clinician's final score for the 2020 MIPS payment year, and under § 414.1330(b)(3), we state that performance in the quality performance category will comprise 45 percent of a MIPS eligible clinician's final score for MIPS payment year 2021. Section 1848(q)(5)(E)(i)(I) of the Act, as amended by section 51003(a)(1)(C)(i) of the Bipartisan Budget Act of 2018, provides that 30 percent of the final score shall be based on performance for the quality performance category, but that for each of the 1st through 5th years for which MIPS applies to payments, the quality performance category performance percentage shall be increased so that the total percentage points of the increase equals the total number of percentage points that is based on the cost performance category performance is less than 30 percent for the respective year. As discussed in section III.K.3.c.(2) of this final rule, we proposed to weight the cost performance category at 20 percent for the 2022 MIPS payment year, 25 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. Accordingly, we proposed to add § 414.1330(b)(4) to provide that performance in the quality performance category will comprise 40 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year. In addition, we proposed at § 414.1330(b)(5) to state that the quality performance category comprises 35 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year. Lastly, we proposed to add § 414.1330(b)(6) to state that the quality performance category comprises 30 percent of a MIPS eligible clinician's final score for the 2024 MIPS payment year and future years. We believe that being transparent in how both the quality and cost performance category weights will be modified over the next few years of the program will allow stakeholders to better plan and anticipate how eligible clinicians and group scores will be calculated in future years as we incrementally make changes to the final score weights.

We received public comments on our proposals to incrementally reduce the weight of the quality performance category as we gradually increase the weight of the cost performance category. The following is a summary of the comments we received and our responses.

Comment: A few commenters urged CMS to maintain the quality performance category weight at 45 percent for the 2020 MIPS performance period to allow for time to address underlying methodological and attribution issues related to the cost measures.

Response: After consideration of the concerns we have heard on the cost measures within the cost performance category, as discussed in section III.K.3.c.(2) of this final rule, we have decided to retain the quality performance category weight at 45 percent for the 2020 performance period. We will revisit changes to the quality and cost performance category weights through future rulemaking.

Comment: A few commenters supported the proposal to decrease the weight of the quality category to 40 percent for the 2020 MIPS performance period and to 35 percent for the 2021 MIPS performance period.

Response: We appreciate the commenters' support. However, after consideration of the concerns we have heard on the cost performance category, as discussed in section III.K.3.c.(2) of this final rule, particularly the concerns on feedback frequency, we have decided to finalize the quality performance category weight at 45 percent for the 2020 performance period. We will revisit changes to the quality and cost performance category weights through future rulemaking.

Comment: A few commenters opposed the proposal to increase the weight of the cost category to 20 percent during the 2020 performance year. One commenter opposed proposed changes to the quality performance category for the 2020–2022 MIPS performance periods because it sends the wrong message to clinicians and patients.

Response: After consideration of the concerns we have heard on the cost measures within the cost performance category, as discussed in section III.K.3.c.(2) of this final rule particularly on the concerns of feedback frequency, we have decided to retain the quality performance category weight at 45 percent for the 2020 performance period. We do not believe that changes to the quality performance category weight will send the wrong message to clinicians and patients, as we believe there are benefits to both cost and quality measurement. We will revisit changes to the quality and cost performance category weights through future rulemaking.

As a result of the comments, we are not finalizing our proposals. Therefore, the quality performance category will comprise 45 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year. We will revisit changes to the quality performance category's weights through future rulemaking and intend on providing additional education and outreach on how eligible clinicians can prepare to meet the incremental shifts in the quality and cost performance category weights.

(c) Quality Data Submission Criteria

(i) Submission Criteria for Groups Electing To Report the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

We did not propose any changes to the established submission criteria for the CAHPS for MIPS Survey. We refer readers to the CY 2019 PFS final rule (83 FR 59756) for previously finalized policies regarding the CAHPS for MIPS survey. Although we did not make any proposals in regard to the CAHPS for MIPS survey in the CY 2020 PFS proposed rule, we solicited comments on numerous areas on how to expand the survey in future years (84 FR 40746 through 40747). While we are not summarizing and responding to comments we received in this final rule, we thank the commenters for their responses and may take them into account as we develop future policies for the CAHPS for MIPS survey.

(ii) Data Completeness Criteria

We refer readers to the CY 2019 PFS final rule (83 FR 59756 through 59758) where we discuss and codified at § 414.1340 finalized data completeness criteria.

As described in the CY 2018 Quality Payment Program final rule (82 FR 53632 through 53634), we anticipated on proposing increases to the data completeness thresholds for data submitted on quality measures (QCDR measures, MIPS CQMs, eCQMs, and Medicare Part B Claims measures) in future years of the program. For MIPS payment years 2019 and 2020, the data completeness threshold was finalized and retained at 50 percent. We provided an additional year for individual MIPS eligible clinicians and groups to gain experience with MIPS before increasing the data completeness threshold for MIPS payment year 2021, for which the

data completeness threshold was finalized at 60 percent.

As discussed in the CY 2020 PFS proposed rule (84 FR 40747 through 40748), we continue to believe it is important to incorporate higher data completeness thresholds over time to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures. We previously noted concerns raised about the unintended consequences of accelerating the data completeness thresholds too quickly, which may jeopardize a MIPS eligible clinicians' ability to participate and perform well under MIPS. We want to ensure that an appropriate yet achievable data completeness is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the 2017 performance period of MIPS, as described in Table 42, we believe that it is feasible for eligible clinicians and groups to achieve a higher data completeness threshold.

TABLE 42—CY 2017 DATA COMPLETENESS RATES FOR MIPS INDIVIDUAL ELIGIBLE CLINICIANS, GROUPS, AND SMALL PRACTICES

Average data completeness rate—individual eligible clinician	Average data completeness rate—groups	Average data completeness rate—small practices
76.14	85.27	74.76

With the support of the data in Table 42, and as described in the CY 2020 PFS proposed rule (84 FR 40748), we proposed to amend § 414.1340 to add paragraph (a)(3) to adopt a higher data completeness threshold for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, and eCQMS must submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2020 MIPS performance period. While we proposed the update to the data completeness threshold for QCDR measures, MIPS CQMs, and eCQMs, we inadvertently did not include the regulation text for § 414.1340(a)(3) in the CY 2020 PFS proposed rule. Therefore, we have included regulation text for § 414.1340(a)(3) within this final rule to state that at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2022 MIPS payment year. As we observe increased use of electronic methods of reporting, such as EHRs and QCDRs, we believe it is important to continue to increase the data completeness threshold, and are interested in stakeholder feedback on an appropriate incremental approach, and on how this incremental increase should be implemented.

In addition, in the CY 2020 PFS proposed rule (84 FR 40745), we proposed to increase the data completeness criteria for Medicare Part B Claims to 70 percent for the 2020 payment year as described in § 414.1340(b)(3). In Table 36 ''Summary of Data Completeness Requirements and Performance Period by Collection type for the 2020 MIPS Performance Period'' of the CY 2020 PFS proposed rule (84 FR 40748), the Medicare Part B Claims collection type is shown to have a performance period of January to December, and that the data completeness is at a 70 percent sample of individual MIPS eligible clinician's or group's Medicare Part B patients for the performance period. While we proposed the update to the data completeness threshold for Medicare Part B Claims, we inadvertently did not include the regulation text for § 414.1340(b)(3) in the CY 2020 PFS proposed rule. Therefore, we have included regulation text for § 414.1340(b)(3) within this final rule to state that at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2022 MIPS payment year.

In crafting our proposal, we also considered other thresholds, such as a higher threshold of 80 percent, but have concerns that requiring every clinician or group to adhere to an increased data completeness threshold that is increased by such a large amount may be considered burdensome to clinicians. We also requested comments on other considerations or possible thresholds we should consider, such as whether we should increase the data completeness threshold to 80 percent to provide for more accurate assessments of quality.

We received public comments on our proposal to increase the data completeness threshold for the quality performance category. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to increase the data completeness threshold, stating that the reporting of complete data is an important step in ensuring that performance is assessed accurately and that increasing data completeness will continue to convey the importance of quality reporting on all patients and potentially help establish benchmarks for new measures. A few commenters supported the increased threshold for data completeness to 70 percent for several reasons, including the ability to improve the data that individual eligible clinicians and groups submit to registries. One commenter indicated that MIPS is currently structured so that practices who choose their measures often times choose those measures that are easy to collect and report as part of their existing clinical workflows. Some commenters expressed appreciation for basing our proposal on data from the field and some noted that many providers are reporting 100 percent of their data at this point. Commenters urged us to continue using a data driven approach to increasing thresholds in the future.

Response: We appreciate the commenters' support and agree that an increase in the data completeness threshold will allow for a more accurate depiction in care and data provided to CMS, whether that is directly or through a third party intermediary. Our intention is to work to ensure that the quality measures used within the MIPS program are relevant and meaningful in a clinician's practice, and appreciate that stakeholders are at ease with incorporating these quality metrics into their existing clinical workflows. In addition, we intend to continue utilizing a data driven approach to increasing the data completeness thresholds in the future.

Comment: A few commenters supported the proposal to increase the data completeness thresholds for four of the six MIPS data collection types from 60 percent to 70 percent of the clinician or group's patients that meet measure denominator criteria, and encouraged CMS to continue using a data-driven approach to increasing thresholds in the future.

Response: We agree the reporting of complete data is essential in ensuring

that MIPS performance is assessed accurately. We plan to continue a data-driven approach to increasing the data completeness threshold in the future.

Comment: Commenters noted to better enable eligible clinicians and groups to meet this higher threshold, CMS should ensure there is a sufficient number of applicable measures to choose from in the program. As CMS increases the data completeness threshold, the agency should also amend the timeline for MIPS CQMs and QCDR measures to be publicly posted.

Response: As noted in section III.K.3.c.(1)(d) of this final rule, as we review the MIPS quality measure inventory for updates, we utilize multiple factors when determining whether a quality measure should be removed or added to the program. As a part of our decision making, we do consider the number applicable measures remaining for clinicians to consider. We will take into consideration the commenters' suggestion of posting measure specifications for both the MIPS quality and QCDR measures earlier than the existing timeframes.

Comment: A few commenters opposed the proposed increase and requested clarifications. One commenter requested clarification as to whether the data used by CMS to support the policy represents all MIPS eligible clinicians across all reporting mechanisms, or represents a subset, such as claims. Another commenter stated their belief that the average rate of reporting is actually less than 70 percent because the statistic does not include data on patients not captured in registries or EHRs (which we understand to refer to data that does not include patients captured through claims data or are not electronically derived). One commenter noted that it was unclear from the data presented in the rule whether the average data completeness rate reflects Medicare only reporting or reporting across all payers.

Response: The data used to support the increase in the data completeness threshold is reflective of all-payer data across all collection types, and is not just reflective of claims. The data completeness threshold under the legacy Physician Quality Reporting System (PQRS) program was at 80 percent, and historical data demonstrated that eligible clinicians had no issue with meeting that threshold. Since MIPS began as a new program in 2017, the data completeness threshold was lowered to allow for time for eligible clinicians and groups to become acclimated to the program. Since we will be entering year 4 of the program, we believe we have given eligible clinicians and groups sufficient time to become oriented to the program. In addition, as described above, we have come across instances where stakeholders, including third-party intermediaries have sought to use data selection criteria to misrepresent a clinician or group's performance for a performance period, commonly referred to as ''cherry-picking,'' resulting in data that is not true, accurate, or complete. Therefore, we believe it is appropriate to finalize the increase to the data completeness threshold to 70 percent.

Comment: One commenter expressed concern that there is no CMS guidance on how to select the percentage of patients they want to report on, and stated the lack of guidance leads to an inconsistent way of submitting data.

Response: We disagree. The data submission and data completeness requirements at §§ 414.1335 and 414.1340 and the guidance we provide in the 2019 MIPS Quality User Guide on the Quality Payment Program Resource Library (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/558/2019%20MIPS%20Quality%20User%20Guide.pdf*) provides guidance as to how clinicians can submit in a consistent manner. We do not specify a methodology for how eligible clinicians can select the patients they want to report on because we believe some operational flexibility is appropriate provided the approach adopted is consistent with our regulations and guidance and does not allow ''cherry picking'' of data.

Comment: Some commenters noted that some measures require a large amount of data collection, and suggested that reporting at this level will force practices—particularly small practices—to invest significant time and money in systems and infrastructures to collect and report data as electronic health records may not capture the necessary data elements or submit the required data.

Response: We are aware that some quality measures require larger volumes of data over others such as those measures that are visit specific or require a follow-up within a specified timeframe. However, the data completeness threshold focuses on the percentage of eligible patients about whom the clinician must report data. With regards to the burden the data completeness threshold may cause for small practices, as indicated in the average data completeness table, we believe small practices are already exceeding the existing data completeness threshold and there will be no additional burden on the part of small practices.

Comment: A few commenters expressed concern that it is unnecessarily complex and burdensome to increase the data completeness threshold when participants are already facing a switch to MIPS Value Pathways (MVPs).

Response: While we understand that eligible clinicians will eventually transition to MVPs, it is important to note that this transition is not occurring for the 2020 performance period. Therefore, we believe it is important to continue to increase the data completeness threshold over time to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures.

After consideration of the comments, we are finalizing our proposal to amend § 414.1340 to add paragraph (a)(3) to adopt a higher data completeness threshold for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2022 MIPS payment year. In addition, we are also finalizing our proposal to amend § 414.1340 to add paragraph (b)(3) for Medicare Part B Claims, to state that, at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2022 MIPS payment year. Through future rulemaking, we intend on increasing the data completeness threshold to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures. In addition, we are making a technical edit to § 414.1340(a)(1) to revise ''the MIPS payment years 2019'' to ''MIPS payment year 2019'' to state at § 414.1340(a)(1), at least 50 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the MIPS payment year 2019. Furthermore, we are making an additional technical edit to § 414.1340(a)(2) to revise ''the MIPS payment years 2020 and 2021'' to ''MIPS payment years 2020 and 2021'' to state at § 414.1340(a)(2), at least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2020 and 2021.

As discussed in the CY 2020 PFS proposed rule (84 FR 40748), we have received inquiries regarding perceived opportunities to selectively submit

MIPS data that are unrepresentative of a clinician or group's performance, suggesting that certain parties may have misunderstood the intent of our incremental approach to the data completeness thresholds, and may not fully appreciate their current regulatory obligations. As stated in §§ 414.1390(b) and 414.1400(a)(5), all MIPS data submitted by or on behalf of a MIPS eligible clinician, group, or virtual group must be certified as true, accurate and complete. MIPS data that are inaccurate, incomplete, unusable, or otherwise compromised can result in improper payment. Using data selection criteria to misrepresent a clinician or group's performance for a performance period, commonly referred to as ''cherry-picking,'' results in data that are not true, accurate, or complete. Accordingly, we proposed to amend § 414.1340 to add a new paragraph (d) to clarify that if quality data are submitted selectively such that the data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5). We received no comments on this proposal and are finalizing this text as proposed. We believe this clarification will emphasize to all parties that the data submitted on each measure is expected to be representative of the clinician's or group's performance and free of selection bias.

We continue to urge all MIPS eligible clinicians to report on quality measures where they have performed the quality actions with respect to all applicable patients.

We note that we did not propose any changes to § 414.1340(c), which states that groups submitting quality measures data using the CMS Web Interface or a CMS-approved survey vendor to submit the CAHPS for MIPS survey must submit data on the sample of the Medicare Part B patients CMS provides, as applicable. We refer readers to the CY 2019 PFS final rule (83 FR 59756 through 59758) for additional discussion of this requirement. Table 43 describes the data completeness requirements by collection type.

TABLE 43: Summary of Data Completeness Requirements and Performance Period by Collection Type for the 2020 MIPS Performance Period

Collection Type	Performance Period	Data Completeness
Medicare Part B claims measures	Jan 1- Dec 31	70 percent sample of individual MIPS eligible clinician's, or group's Medicare Part B patients for the performance period.
QCDR measures, MIPS CQMs, and eCQMs	Jan 1- Dec 31	70 percent sample of individual MIPS eligible clinician's, or group's patients across all payers for the performance period.
CMS Web Interface measures	Jan 1- Dec 31	Sampling requirements for the group's Medicare Part B patients: populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries.
CAHPS for MIPS survey measure	Jan 1- Dec 31	Sampling requirements for the group's Medicare Part B patients.

(d) Selection of MIPS Quality Measures

(i) Call for Measures and Measure Selection Process

In the CY 2019 PFS final rule (83 FR 59758 through 59761), we discuss the importance of classifying measures by meaningful measure areas, and updates to the definition of a high priority measure. We refer readers to the CY 2019 PFS final rule for additional details.

Furthermore, in the CY 2018 Quality Payment Program final rule (82 FR 53635 through 53637), we state that quality measure submissions submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual Call for Measures, which is further described through the CMS Pre-Rulemaking website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.html.* The annual Call for Measures process allows for eligible clinician organizations and other relevant stakeholder organizations to identify and submit quality measures for consideration. Presumably, stakeholders would not submit measures for consideration unless they believe the measures are applicable to clinicians and can be reliably and validly measured. Through the annual convention of the consensus-based entity, stakeholders are given the opportunity provide input on whether or not they believe measures are applicable to clinicians, feasible, scientifically acceptable, reliable, and valid at the clinician level. We intend to continue to submit future MIPS quality measures to the consensus-based entity, as appropriate, and consider the recommendations provided as part of the comprehensive assessment of each measure considered for inclusion in MIPS. In addition, we must go through notice and comment rulemaking to consider stakeholder feedback prior to finalizing the annual list of quality measures. Furthermore, as required by statute, new measures must be submitted to an applicable specialty-appropriate, peer-reviewed journal. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53636) for additional details on the peer-reviewed journal requirement.

In the CY 2018 Quality Payment Program final rule (82 FR 53636), we requested stakeholders apply the following set of considerations when submitting quality measures for possible inclusion in MIPS:

- Measures that are not duplicative of an existing or proposed measure.

- Measures that are beyond the measure concept phase of development, with a strong preference for measures that have completed reliability, feasibility, and validity testing.
- Measures that are outcomes-based rather than process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnoses and therapeutics.
- Measures that address the domain of care coordination.
- Measures that address of patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.
- Measures that address significant variation in performance and are not considered topped out.
- Measures that are specified as a collection type other than Medicare Part B Claims. We encourage measure stewards to keep this in mind as they develop and submit measures for consideration.

We also encourage stakeholders to consider electronically specifying their quality measures, as eCQMs, in order to encourage clinicians and groups to move towards the utilization of electronic reporting, as we believe electronic reporting will increase timeliness and efficiency of reporting by replacing manual data entry.

In addition to the aforementioned considerations, when considering quality measures for possible inclusion in MIPS, we proposed that beginning with the 2020 Call for Measures process, MIPS quality measure stewards would be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible (84 FR 40749). MIPS quality measure stewards will be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities as a part of the Call for Measures process. We recognize there are instances where costs measures are not available for all clinician specialties or that improvement activities may not be associated with a given quality measure. However, we believe that when possible, it is important to establish a strong linkage between quality, cost, and improvement activities.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal that measures stewards should link their quality measures with improvement activities and cost measures when possible. Commenters stated that it might be beneficial for CMS to require the same assessment by an Improvement Activities submitter as the agency would for a new MIPS measure.

Response: We agree that this criteria could be applied to improvement activities as well, and will take it into consideration in future rulemaking.

After consideration of the comments, we are finalizing that beginning with the 2020 Call for Measures process, MIPS quality measure stewards will be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards will be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities as a part of the Call for Measures process.

Furthermore, previously finalized MIPS quality measures can be found in the CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). The new MIPS quality measures proposed for inclusion in MIPS for the 2020 performance period and future years are found in Table Group A of Appendix 1 of this proposed rule.

In addition to the individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with choosing quality measures that are most relevant to their scope of practice. In the CY 2020 PFS proposed rule (84 FR 40749), we erroneously indicated that changes were not made to the Pathology, Electro-Physiology Cardiac Specialist, and Interventional Radiology specialty set. We clarify that we requested comments on the Electro-Physiology Cardiac Specialist specialty set (84 FR 40954) and proposed changes to the Pathology specialty set (84 FR 41020 through 41022). Our proposals for modifications to existing specialty sets and new specialty sets are discussed in Table Group B of Appendix 1 of this final rule. Specialty sets may include: New measures, previously finalized measures with modifications, previously finalized measures with no modifications, the removal of certain previously finalized quality measures, or the addition of existing MIPS quality measures. Please note that the specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 18, 2019,[114] we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for Year 4 of MIPS under the Quality Payment Program. These recommendations were based on the MIPS quality measures finalized in the CY 2019 PFS final rule, the 2019 Measures Under Consideration list, and provides recommendations to add or remove the current MIPS quality measures from existing specialty sets, or provides recommendations for the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and those recommendations that we agree with were proposed in the CY 2020 PFS proposed rule.

In addition, MIPS quality measures with substantive changes can be found in Table Groups D and DD of Appendix 1 of this final rule. As discussed in Table DD of this final rule, we have determined based on extensive stakeholder feedback that the 2018 CMS Web Interface measure numerator guidance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention measure is inconsistent with the intent of the CMS Web Interface version of this measure as modified in the CY 2018 Quality Payment Program final rule (82 FR 54164) and is unduly burdensome on clinicians. Moreover, due to the current guidance, we are unable to rely on historical data to benchmark the measure. Therefore, for the 2018 MIPS performance period and 2020 MIPS payment year, we are excluding the Web Interface version of this measure from MIPS eligible clinicians' quality scores in accordance with § 414.1380(b)(1)(i)(A)(2). Beginning with reporting for the 2019 MIPS performance period and 2021 MIPS payment adjustment, we proposed in Table DD of this final rule to update the CMS Web Interface measure numerator guidance. To the extent that this change constitutes a change to the MIPS scoring or payment methodology for the 2021 MIPS payment adjustment after the start of the 2019 MIPS performance period, we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to

[114] Listserv messaging was distributed through the Quality Payment Program listserv on January 18th, 2019, titled: ''CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets for the Quality Performance Category and/or Revisions to the Existing Specialty Measure Sets for the Quality Performance Category for the 2020 Program Year of Merit-based Incentive Payment System (MIPS).''

modify the measure in Table DD of this final rule because the current guidance is inconsistent with the intent of the CMS Web Interface version of this measure, as modified in the CY 2018 Quality Payment Program final rule, and unduly burdensome on clinicians. As discussed in Table DD of this final rule, we are finalizing this modification as proposed and expect that we will be able to benchmark and score the CMS Web Interface version of this measure for the 2019 MIPS performance period and 2021 MIPS payment adjustment. Furthermore, we refer readers to section III.E.1.b. of this final rule for a discussion on how the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention quality measure will be scored for the Medicare Shared Savings Program.

In addition, also as discussed in section III.E.1.b of this final rule, changes to the CMS Web Interface measures for MIPS that are proposed and finalized through rulemaking would also be applicable to ACO quality reporting under the Medicare Shared Savings Program. As discussed in Table Group A of Appendix 1 of this final rule, we proposed to add 1 new measure to the CMS Web Interface in MIPS. Furthermore, as discussed in Table Group C of Appendix 1 of this final rule, we proposed to remove 1 measure from the CMS Web Interface in MIPS. As discussed in Table Groups A and C of Appendix 1 of this final rule, we are not finalizing our proposed measure additions and removals for the CMS Web Interface in MIPS. Groups reporting CMS Web Interface measures for MIPS will be responsible for reporting the finalized measure set. We refer readers to the Appendix 1 of this final rule for additional details on the proposals related to changes in CMS Web Interface measures.

On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive as described above. We note that the current cycle of measure updates to MIPS quality measures is separate from the eCQM annual update process. An overarching timeline of milestones related to eCQMs available at *https://ecqi.healthit.gov/ecqm-annual-timeline.* We solicited stakeholder comment as to whether we should consider realigning the measure update cycle with that of the eCQM annual update process. While we are not summarizing and responding to comments we received in this final rule, we appreciate the responses and may take them into account as we develop future policies for the measure update process.

In addition, we referred readers to the CY 2019 PFS final rule (83 FR 59759) for additional details on reporting requirements of eCQM measures. Furthermore, as discussed in section III.D. of this final rule, we proposed to generally align the CY 2020 eCQM reporting requirements for the eligible professionals participating in the Medicaid Promoting Interoperability Program with the MIPS eCQM reporting requirements. We refer readers to section III.D. of this final rule for additional details and criteria on the Medicaid Promoting Interoperability Program proposals.

(ii) Global and Population-Based Measures

Section 1848(q)(2)(C)(iii) of the Act provides that the Secretary may use global measures, such as global outcome measures, and population-based measures for purposes of the quality performance category. We believe the purpose of global and population-based measures is to encourage systemic health care improvement for the populations being served by MIPS eligible clinicians. In addition, as described in the CY 2017 Quality Payment Program final rule (81 FR 77130 through 77136), we believe that all MIPS eligible clinicians, including specialists and subspecialists, have a meaningful responsibility to their communities, which is why we chose to focus on population health and prevention measures for all MIPS eligible clinicians. It is important to note that an individual's health relates directly to population and community health, which is an important consideration for quality measurement in MIPS and in general. Furthermore, we have heard from stakeholders that we should drive quality measurement towards a set of population-based outcome measures to publicly report on quality of care.

In addition, we believe including additional administrative claims based measures in the program will reduce the burden associated with quality reporting. Quality measures that are specified through the administrative claims collection type do not require separate data submission to CMS. Administrative claims measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims. For these reasons, as discussed in Table Group AA of Appendix 1 of this final rule, we proposed the inclusion of a population health based quality measure (the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure) beginning with the 2021 MIPS performance period. We proposed this measure with a delayed implementation until the 2021 performance period of MIPS, to allow for time to work through operational factors of implementing the measure. Factors include allowing for time for the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure to go through the Measures Under Consideration and Measures Application Partnership (MAP) process that is typically applied for all MIPS quality measures. We refer readers to section III.K.3.a. of this final rule for additional information on our interest to include other global and population-based measures in future years of MIPS, which we envision would include the modification of the submission requirements under the quality performance category.

We received public comments on our proposal to include global and population-based measures. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the inclusion of population health quality measures in a clinician-focused program based on the belief that they could reduce the opportunity for improvements in patient outcomes, are unable to be tracked in real time, are outside of individual clinician's control, and require a large sample size to produce reliable data.

Response: We disagree. We believe the purpose of global and population-based measures is to encourage systemic health care improvement for the populations being served by MIPS eligible clinicians. In addition, as described in the CY 2017 Quality Payment Program final rule (81 FR 77130 through 77136), we believe that all MIPS eligible clinicians, including specialists and subspecialists, have a meaningful responsibility to their communities, which is why we chose to focus on population health and prevention measures for all MIPS eligible clinicians. We disagree with commenters who believe that population health quality measures reduce the opportunity for improvements in patient outcomes and are unable to be tracked in real time. We believe population health measures increase opportunities to improve patient outcomes on a systemic health level for the populations being served by MIPS eligible clinicians, and that the ability to be tracked in real time is important, but even without real time tracking, we still see a benefit to including these measures in the

program. In addition, while administrative claims based measures may use a large sample size of data, the data collection is less burdensome than what is used for other collection types, since it is done without any submission required by the eligible clinician or group. It is important to note that population and community health may directly influence an individual's health, which is an important consideration for quality measurement in MIPS and in general. In addition, we believe that including additional administrative claims based measures in the program will reduce the burden associated with quality reporting. Quality measures that are specified through the administrative claims collection type do not require separate data submission to CMS. Administrative claims measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims. We intend on incrementally including population-based measures into MIPS, and will be looking to evaluate and address stakeholder concerns as a part of the process.

Comment: A few commenters expressed concern about the use of these measures in this clinician-focused program due to their belief of inadequate risk adjustment and lack of consideration of social risk factors and complex patients.

Response: We appreciate the feedback on the role risk adjustment, and complex patients in quality measurement. We continue to evaluate the potential impact of social risk factors on measure performance. One of our core objectives is to improve beneficiary outcomes. We want to ensure that complex patients, as well as those with social risk factors receive excellent care. While we believe the MIPS measures are valid and reliable, we will continue to investigate methods to ensure all clinicians are treated as fairly as possible within the program.

Comment: One commenter opposed the inclusion of the All-Cause Unplanned Admission for Patients with MCCs beginning with the 2021 MIPS performance period with the rationale that because fraud and abuse laws impose restrictions on options for care coordination, it is inappropriate to have a quality measure that presumes effective care coordination.

Response: We believe that the level of care coordination needed to perform well on this quality measure is possible within the existing fraud and abuse framework.

Comment: Several commenters did not support the proposed adoption of the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions due to the belief that the measure lacks alignment and reliable attribution. Several commenters expressed concern that the measure does not provide actionable or meaningful feedback to clinicians, such as surgeons and specialists, while holding them accountable for admissions. One commenter recommended that the measure be reviewed by the MAP and NQF.

Response: We appreciate the commenters' concerns regarding the measure's alignment and attribution, and the need for actionable feedback on the measures. We are not finalizing this measure for the 2021 MIPS performance period/2023 MIPS payment year in this final rule, in order to work on addressing the commenters' feedback and to allow for the measure to be reviewed at the NQF's Measure Application Partnership meeting.

After consideration of the comments, we are not finalizing the inclusion of the population health based All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure, and will seek to propose it through future rulemaking once we are able to consider feedback from the MAP on this measure.

(iii) Topped Out Measures

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53637 through 53640), where we finalized the 4-year timeline to identify topped out measures, after which we may propose to remove the measures through future rulemaking. We also refer readers to the 2019 MIPS Quality Benchmarks' file that is located on the Quality Payment Program resource library (*https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html*) to determine which measure benchmarks are topped out for 2019 and would be subject to the scoring cap if they are also identified as topped out in the 2020 MIPS Quality Benchmarks' file. We note that the final determination of which measure benchmarks are subject to the topped out cap would not be available until the 2020 MIPS Quality Benchmarks' file is released in late 2019, but will eventually be posted on the Quality Payment Program Resource Library at *https://qpp.cms.gov/about/resource-library.*

In the CY 2019 PFS final rule (83 FR 59761 through 59763), we finalized that once a measure has reached extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle. However, we would also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to the Agency). In the CY 2020 PFS proposed rule (84 FR 40750), we erroneously indicated that we were not removing extremely topped out measures from the Pathology specialty set. We clarify that we proposed to remove four extremely topped out measures from and add one measure to the Pathology set in Appendix 1 of the proposed rule (84 FR 41020 through 41022).

Quality measures identified as extremely topped out are considered to have high, unvarying performance where no meaningful room for improvement can be identified, and are only identified as such through data received during the submission period. We have heard from stakeholders that some measures tend to appear topped out or extremely topped out due to clinicians' ability to select measures they expect to perform well on, and because of this, the data we receive is not actually representative of how clinicians perform across the country on these metrics. For this reason, we solicited comment on whether we should increase the data completeness threshold for quality measures that are identified as extremely topped out, but are retained in the program due to the limited availability of quality measures for a specific specialty. In addition, we solicited comment on potential alternative solutions in addressing extremely topped out measures. While we are not summarizing and responding to comments we received in this final rule, we appreciate the responses and may take them into account as we develop future policies for extremely topped out measures.

We encourage stakeholders to continue their measure development efforts in creating new pathology specific quality measures that can demonstrate a meaningful performance gap, thereby offering opportunities for quality improvement. We also continue encourage pathologists to consider reporting on pathology specific QCDR measures through a CMS-approved QCDR available for the 2020 performance period. A list of CMS-approved QCDRs for the 2020 performance period will be made available on or prior to January 1, 2020, and will be posted on the Quality

Payment Program resource library at *https://qpp.cms.gov/about/resource-library*.

In addition, in the CY 2019 PFS final rule (83 FR 59761 through 59763), we also finalized our policy to exclude QCDR measures from the topped out measure timeline. When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period.

(iv) Removal of Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we discussed removal criteria for quality measures, including that a quality measure may be considered for removal if the Secretary determines that the measure is no longer meaningful, such as measures that are topped out. Furthermore, if a measure steward is no longer able to maintain the quality measure, it would also be considered for removal. In addition, in the CY 2019 PFS final rule (83 FR 59763 through 59765), we communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set, we believe incrementally removing non-high priority process measures through notice and comment rulemaking is appropriate. We referred readers to the CY 2019 PFS final rule (83 FR 59763 through 59765) for details on the previously established criteria to remove measures.

In addition to previously established measure removal criteria, we have observed instances where MIPS quality measures have had low reporting rates year over year, and have made it difficult for some MIPS quality measures to achieve a benchmark. As a result, these measures have resulted in clinicians receiving no more than 3 points for each measure that is unable to meet benchmarking criteria. For these reasons, we proposed to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods (84 FR 40751 through 40752). We believe that a time period of 2 consecutive CY performance periods is appropriate, as we anticipate that any newly finalized measure would need more than 1 CY performance period in order to observe measure reporting trends, and believe that 2 consecutive CY performance periods allows for sufficient time to monitor reporting volumes. We will factor in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome) prior to determining whether to remove the measure. Removing measures with this methodology ensures that the MIPS quality measures available in the program are truly meaningful and measureable areas, where quality improvement is sought and that measures that are low reported for 2 consecutive CY performance periods are removed from the program. We believe low reported measures can point to that the measure concept does not provide meaningful measurement to most clinicians. If the measure has too few reporting clinicians and does not meet the case minimum and reporting volumes, but other considerations favor retaining the measure, we may consider keeping the MIPS quality measure, with the caveat that the measure steward should have a participation plan in place (prior to approval of the measure) to encourage reporting of the measure, such as education and communication or potentially measure specification changes. In addition, we refer readers to Table Group C of Appendix 1 of this final rule for a list of quality measures and rationales for removal. We have continuously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. We believe our proposal to remove the quality measures outlined in Table Group C will lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to remove measures should occur through an iterative process that will include an annual review of the quality measures to determine whether they meet our removal criteria.

We received public comments on our proposal to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal and expressed appreciation of CMS' move to a parsimonious measure set, with a caution for CMS to ensure each specialty will have enough measures to report in a meaningful manner.

Response: We thank the commenters for their support.

Comment: One commenter stated that eliminating a measure only after 2 years in the program will deter measure stewards from investing in and developing new measures, maintaining existing measures, and putting forward MVP proposals. The commenter indicated the proposed policy would result in removing measures that developers have spent more than 2 years to develop and test only to have it in the program for a small number of years and encouraged CMS to perform analysis and work with measure stewards to learn the time it takes for measures to achieve acceptable numbers of adoption.

Response: While we understand the time it takes for measure stewards to develop and invest in quality measures, we also want to be mindful of the large volume of measures that accrue in our measure inventory year over year. There have been instances where quality measures have been in the MIPS or legacy PQRS program, where the reporting volumes are quite low, and that has been the basis to which we have established this policy. We believe that lowly-reported quality measures do not add value to a clinician's quality improvement strategy, and that having a large volume of measures can increase burden by providing too much choice. We are open to working with measure stewards to understand the time it takes for measures to achieve increased adoption, and would encourage those measure stewards to submit a participation plan for our consideration for measures that have not reached benchmarking thresholds within the 2-year timeframe.

Comment: A few commenters suggested that CMS should assess each measure on a case-by-case basis rather than creating a blanket policy to remove them.

Response: As noted above, as a part of our measure removal process, we intend to assess each measure on a case-by-case basis and will take into consideration multiple factors, including but not limited to: Whether the measure removal will impact the number of measures available to a given specialty; or whether the measure removal will result in no remaining outcome or high priority measures available to a specialty to meet the quality performance category reporting requirements.

Comment: One commenter noted that data from the first 2 years of MIPS is not representative, as reporting requirements and performance thresholds for the program have changed over time.

Response: We disagree. There has been evidence of quality measures that continue to be low-reported over several years, as we have tracked performance on many of these metrics from the

previous legacy program, PQRS. We do not believe low-reported quality measures provide value in a pay for performance quality program.

Comment: A few commenters expressed concern about the proposal to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Commenters stated that low reporting rates are not always an indication of a low value measure. One commenter noted that some measures may only be reported by a small number of clinicians which represents a significant percentage of those caring for a specific patient population, and urged CMS to evaluate these important factors when assessing topped out status and making measure removal determinations. One commenter opposed this proposal and recommended that CMS allow appropriate time for measures to receive enough data to set benchmarks.

Response: As discussed above, we believe that a time period of 2 consecutive CY performance periods is appropriate, as we anticipate that any newly finalized measure would need more than 1 CY performance period in order to observe measure reporting trends, and believe that 2 consecutive CY performance periods allows for sufficient time to monitor reporting volumes. We will factor in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome) prior to determining whether to remove the measure; the measure's relevance for sub-specialists. Removing measures with this methodology ensures that the MIPS quality measures available in the program are truly meaningful and measureable areas, where quality improvement is sought and that measures that are low reported for 2 consecutive CY performance periods are removed from the program. We believe low reported measures can point to that the measure concept does not provide meaningful measurement to most clinicians. If the measure has too few reporting clinicians and does not meet the case minimum and reporting volumes, but other considerations favor retaining the measure, we may consider keeping the MIPS quality measure.

Comment: Several commenters expressed concern about the number of measures proposed for removal, and recommended we maintain as broad an inventory of measures as possible. Several commenters urged CMS to reconsider the proposed removal of 55 quality measures or over 20 percent of the quality category measures, particularly those proposed for removal due to topped out status or an ongoing lack of benchmark. Several commenters noted the removal of specific measures could impact the ability of specialists to participate fully and meaningfully in MIPS and could cause them to re-evaluate investment in developing new MIPS measures.

Response: We have continuously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. We believe our proposal to remove the quality measures outlined in Table Group C will lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to remove measures should occur through an iterative process that will include an annual review of the quality measures to determine whether they meet our removal criteria. as a part of our measure removal process, we intend to assess each measure on a case-by-case basis and will take into consideration multiple factors, including but not limited to: Whether the measure removal will impact the number of measures available to a given specialty or whether the measure removal will result in no remaining outcome or high priority measures available to a specialty to meet the quality performance category reporting requirements. While we intend on removing some quality measures from the program that no longer add value, as noted above, we are finalizing additional quality measures in the program (two patient-reported outcome measures, and one opioid-related measure, as well as the addition of seven new specialty sets, and continuously intend on evaluating the MIPS quality measure inventory on an annual basis.

Based on these considerations, we have decided not to finalize the removal of certain measures (particularly some of those measures that are available to non-patient facing clinicians), and refer readers to Table Group C for detailed discussion on the measures we are no longer removing. We continuously encourage stakeholders to develop measures to not just address measurement gaps, but to also address and replace specialty specific topped out quality measures as we seek to eventually transition to MVPs.

After consideration of the comments, we are finalizing our proposal to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. We will factor in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome; consideration of the measure in developing MVPs) prior to determining whether to remove the measure.

We have heard from stakeholders concerns on removing measures and the need for more notice before a measure is removed. Therefore, we are interested in what factors should be considered in delaying the removal of measures. For example, we have not heard concerns from stakeholders that selection bias may be impacting low reporting rates, we are interested if this is something we should consider, and how we could determine when low-reporting is due to selection bias versus instances where the measure is not a meaningful metric to the majority of clinicians who would have reported on the measure otherwise. We solicited comment on whether we should delay the removal of a specific quality measure by a year, for any of the MIPS quality measures identified for removal. We also requested feedback on which quality measure's removal should be delayed for a year, and why. While we are not summarizing and responding to comments we received in this final rule, we thank the commenters for their responses and may take them into account as we develop future policies for consideration to delay measure removals.

Furthermore, when we finalize measures to be a part of the MIPS quality measure inventory for a given MIPS payment year, we generally intend that the measures will be available for reporting by or on behalf of all MIPS eligible clinicians since MIPS is a government quality reporting program. It has come to our attention that certain MIPS measure stewards have limited or prohibited the use of their measures by third party intermediaries such as QCDRs and qualified registries. To the extent that MIPS measure stewards limit the availability of previously finalized measures for MIPS quality reporting, including reporting by third party intermediaries on behalf of MIPS eligible clinicians, these limitations may lead to inadvertent increases in burden both for the MIPS eligible clinicians who rely on third party intermediaries and for third party intermediaries themselves. In addition, these limitations may adversely affect our ability to benchmark the measure or the robustness of the benchmark. For these reasons, we proposed to adopt an additional removal criterion, specifically, that we may consider a

MIPS quality measure for removal if we determine it is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians. We solicited comments on this proposal.

We received public comments on whether to adopt an additional removal criterion, specifically, that we may consider a MIPS quality measure for removal if we determine it is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted their support for our proposal to consider measures for removal if a measure steward does not make their measure available for reporting by or on behalf of all MIPS eligible clinicians it should be considered for removal.

Response: We thank the commenters for their support.

After consideration of the comments, we are finalizing the proposed measure removal criterion that we may consider a MIPS quality measure for removal if we determine it is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians.

(v) Request for Information on Potential Opioid Overuse Measure

To address concerns associated with long-term, high-dose opioids, we developed an electronic clinical quality measure (eCQM) titled: Potential Opioid Overuse. In the CY 2020 PFS proposed rule (84 FR 40752), we solicited stakeholder feedback in several areas related to this measure. While we are not summarizing and responding to comments we received in this final rule, we thank the commenters for their responses and may take them into account as we consider further development of the Potential Opioid Overuse measure.

(2) Cost Performance Category

For a description of the statutory basis and our existing policies for the cost performance category, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 PFS final rule (81 FR 77162 through 77177, 82 FR 53641 through 53648, and 83 FR 59765 through 59776, respectively).

In the CY 2020 PFS proposed rule (84 FR 40752 through 40762), we proposed to:

- Weight the cost performance category at 20 percent for MIPS payment year 2022, 25 percent for MIPS payment year 2023, and 30 percent for MIPS payment year 2024 and all subsequent MIPS payment years;
- Change our approach to proposing attribution methodologies for cost measures by including the methodology in the measure specifications;
- Add 10 episode-based measures;
- Modify the total per capita cost and Medicare Spending Per Beneficiary (MSPB) measures; and
- Requested comments on the future inclusion of an additional episode-based measure.

These proposals are discussed in more detail in the following sections of this final rule.

(a) Weight in the Final Score

In the CY 2019 PFS final rule, we established at § 414.1350(d)(3) that the weight of the cost performance category is 15 percent of the final score for the 2021 MIPS payment year (83 FR 59765 through 59766). Section 51003(a)(1)(C) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA of 2018) amended section 1848(q)(5)(E)(i)(II)(bb) of the Act such that for each of the second, third, fourth, and fifth years for which the MIPS applies to payments, not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category score. Additionally, section 1848(q)(5)(E)(i)(II)(bb) of the Act as amended states that it shall not be construed as preventing the Secretary from adopting a 30 percent weight if the Secretary determines, based on information posted under section 1848(r)(2)(I) of the Act, that sufficient cost measures are ready for adoption for use under the cost performance category for the relevant performance period. In the CY 2019 PFS proposed rule, we solicited comments on how we should weight the cost performance category for the 2022 and 2023 MIPS payment years given the changes within the BBA of 2018 (83 FR 35901). We considered these comments when we developed our proposals for setting the weight of the cost performance category.

In the CY 2020 PFS proposed rule (84 FR 40752), we proposed a steady increase in the weight of the cost performance category from the existing weight of 15 percent for the 2021 MIPS payment year to 30 percent beginning with the 2024 MIPS payment year as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act. We stated that we believe this gradual and predictable increase would allow clinicians to adequately prepare for the 30 percent weight while gaining experience with the new cost measures. We recognized that cost measures are still being developed and that clinicians may not have the same level of familiarity or understanding of cost measures that they do of comparable quality measures. We also recognized that there may be greater understanding of the measures in the cost performance category as clinicians gain more experience with them.

We proposed at § 414.1350(d)(4) that the cost performance category would make up 20 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year (84 FR 40752). We stated that we plan to increase the weight of the cost performance category at standard increments of 5 percent each year until MIPS payment year 2024. Therefore, we proposed at § 414.1350(d)(5) to weight the cost performance category at 25 percent for the 2023 MIPS payment year and proposed at § 414.1350(d)(6) to weight the cost performance category at 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year (84 FR 40752). This would allow us to meet the 30 percent cost performance category weight when required by the statute and give clinicians adequate time to gain experience with the cost measures while they represent a smaller portion of the final score. We stated that we also believe that a predictable increase in the weight of the cost performance category each year would allow clinicians to better prepare for each year going forward. We noted that we considered maintaining the weight of the cost performance category at 15 percent for the 2022 and 2023 MIPS payment years as we recognize that we are still introducing new measures for the cost performance category and clinicians are still gaining familiarity and experience with these new measures. However, recognizing that we are required by the statute to weight the cost performance category at 30 percent beginning with the 2024 MIPS payment year, we are concerned about having to increase the cost performance category's weight significantly for the 2024 MIPS payment year. We invited comments on whether we should consider an alternative weight for the 2022 and/or 2023 MIPS payment years.

The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal to gradually increase the weight of the cost performance category to 20 percent for the 2022 MIPS payment year, 25 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year.

Response: We thank the commenters for their support.

Comment: Some commenters suggested maintaining the cost performance category weight at 15 percent until CMS is able to provide more detailed and actionable performance data to clinicians. Some examples of more detailed feedback include comparison information and data on the MIPS 2019 performance period cost measures or a format similar to the Quality and Resource Use Reports (QRURs) that were made available in connection with the Physician Quality Reporting System (PQRS) and Value Modifier (VM) programs. Some commenters suggested that CMS should wait to increase the weight of the cost performance category until clinicians gain more experience with and are more educated about the proposed and newly developed episode-based measures, and the modified total per capita cost and MSPB measures.

Response: We agree with this concern and believe clinicians need more detailed and timely feedback on both new and existing cost measures in order to improve their performance in the cost performance category. We previously made the QRURs available to clinicians under the Physician Feedback Program, but the statute required those reports to end with 2017. In July of 2019, we provided detailed performance feedback reports to clinicians which included detailed information reflecting performance for the total per capita cost measure and MSPB clinician measure as specified for the 2018 MIPS performance period. We intend to provide similar feedback for all cost measures in July of 2020, reflecting performance from the 2019 MIPS performance period and utilizing the measure specifications applicable for the 2019 MIPS performance period. We are committed to improving the feedback experience, including aiming to provide more granular and real-time data, for clinicians to better understand how they can improve their performance on these measures and in turn reduce the cost of care for Medicare beneficiaries. Once clinicians better understand and are more accustomed to reviewing the performance feedback reports on these episode-based and global cost measures, we would then expect to increase the cost performance category weight. Therefore, we believe it is best to maintain the 15 percent weight for the cost performance category for MIPS payment year 2022 in efforts to allow clinicians to become more familiar with the feedback process and allow us to continue to improve feedback reports.

Comment: Many commenters opposed our proposal to gradually increase the weight of the cost performance category by 5 percent until MIPS payment year 2024 and utilize the flexibility established by the Bipartisan Budget Act of 2018 to weight the cost performance category between 10 and 30 percent. Some commenters expressed general concern about the quality of measures in the cost performance category including issues with appropriate attribution, reliability, and adjustment for social and complexity risk factors. Other commenters expressed concern about continued change and development in cost measures. A few commenters urged CMS to not increase the cost performance category weight in 2020 in light of the transition period to MVPs.

Response: We understand that for many clinicians, cost measures are more difficult to understand than measures and activities in other performance categories. We believe that we can help to facilitate understanding by providing a more detailed level of feedback on performance on these measures. While we believe it is important to provide more detailed performance feedback to clinicians before increasing the weight of the cost performance category, we do not believe that the introduction of new and revised measures would require us to minimize the weight of the cost performance category. As in all performance categories of MIPS, there are continued opportunities to improve the measures and activities used to assess performance. We do believe that the cost measures that we are using in MIPS represent the best available measures and we take care to consider all of the important issues mentioned by the commenters, including attribution and risk adjustment, as part of the measure development process. Specifically regarding social and complexity risk factors, we continue to investigate ways to best accommodate the issue of social and patient complexity adjustment in measures. Currently, we use the CMS–HCC model to account for patient complexity, and we have also established a complex patient bonus as part of the MIPS final score, which accounts for elements of social complexity. We refer readers to our comment responses in section III.K.3.c.(2)(b)(iii) of this final rule for more detailed explanation of how we continue to address this issue.

We also continue to revise measures to address concerns with attribution methodologies as discussed in section III.K.3.c.(2)(b)(v) of this final rule. In regards to reliability, we believe our current reliability threshold of 0.4 for measures in the cost performance category is both consistent with other CMS quality programs and ensures moderate reliability but does not substantially limit participation. We further discuss our policies related to reliability for cost measures in section III.K.3.c.(2)(b)(vi) of this final rule. Lastly, we anticipate that we may continue to use many of these proposed and newly developed episode-based measures within MVPs.

Comment: A few commenters recommended maintaining the cost performance category weight at 15 percent until CMS develops more reliable and valid measures. One commenter stated that the cost methodology does not appropriately capture the cost of care for certain specialties particularly those that deliver costly procedures and treat highly complex patients.

Response: We agree that it is important to have measures that are as reliable and valid as possible in the cost performance category. We have focused our efforts on developing episode-based measures, with significant clinical input to ensure that they reflect the services that can most be affected by the clinicians during the episode. We have also, as discussed in section III.K.3.c.(2)(b)(v) of this final rule, refined the existing total per capita cost and Medicare spending per beneficiary in a manner that we believe improves their validity. We will continue to evaluate cost measures that are included in MIPS on an ongoing basis and anticipate that measures could be added, modified, or removed through rulemaking as measure development continues. Additionally, we continue to work to develop new episode-based measures that could be considered for inclusion in the cost performance category in future years. We expect that future measures may apply to a greater range of specialties and clinical areas, including those that deliver costly procedures as suggested by commenters. However, once again, while we believe it is important to provide more detailed performance feedback to clinicians before increasing the weight of the cost performance category, we do not believe that the introduction of new and revised measures would require us to minimize the weight of the cost performance category. Section 1848(r)(2)(D)(i)(I) of the Act requires us to establish care episode groups and patient condition groups, which account for a target of an estimated one half of expenditures under parts A and B with such target increasing over time as appropriate. While we have developed some episode-based measures to target that goal as required, we shall continue our work to develop additional measures focusing on both additional specialty

types, as well as consider the important issue of treating highly complex patients. By continuing to gather detailed clinician and expert input on episode-based measures, such as through clinical subcommittees and technical expert panels convened by the measure development contractor, we hope to identify and mitigate potential unintended consequences each stage of the measure development process.

After consideration of the public comments, we are not finalizing our proposal at § 414.1350(d)(4) that the cost performance category would make up 20 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year. For the reasons discussed in our responses to comments above, we are instead continuing to weight the cost performance category at 15 percent for the 2022 MIPS payment year and are revising § 414.1350(d)(3) to reflect that the cost performance category will be 15 percent of a MIPS eligible clinician's final score for MIPS payment years 2021 and 2022. We are also not finalizing our proposals at § 414.1350(d)(5) to weight the cost performance category at 25 percent for the 2023 MIPS payment year and at § 414.1350(d)(6) to weight the cost performance category at 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. We will consider the state of the performance feedback that we offer clinicians and expect to propose a weight for the cost performance category for the 2023 MIPS payment year in the CY 2021 PFS proposed rule.

In accordance with section 1848(q)(5)(E)(i)(II)(bb) of the Act, we will continue to evaluate whether sufficient cost measures are included under the cost performance category as we move towards the required 30 percent weight in the final score. As described in section III.K.3.c.(2)(b)(iii) of this final rule, we proposed to add 10 episode-based measures to the cost performance category beginning with the 2020 MIPS performance period (84 FR 40754 through 40759). We are continuing our efforts to develop more robust and clinician-focused cost measures. We will also be continuing to work on developing additional episode-based measures that we may consider proposing for the cost performance category in future years to address additional clinical conditions. Introducing more measures over time will allow more clinicians to be measured in this performance category, with an increasing focus on capturing costs for clinically associated services provided by clinicians for specific episodes of care. In section III.K.3.c.(2)(b)(v) of the proposed rule, we discussed modifications to both the total per capita cost and MSPB measures in an effort to ensure that our existing cost measures hold clinicians appropriately accountable (84 FR 40757 through 40759).

(b) Cost Criteria

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. We will continue to evaluate cost measures that are included in MIPS on an ongoing basis and anticipate that measures could be added, modified, or removed through rulemaking as measure development continues. Any substantive changes to a measure would be proposed for adoption in future years through notice and comment rulemaking, following review by the Measure Applications Partnership (MAP). We would take all comments and feedback from both the public comment period and the MAP review process into consideration as part of the ongoing measure evaluation process. In the CY 2020 PFS proposed rule, we proposed to add 10 newly developed episode-based measures to the cost performance category for the CY 2020 performance period and future performance periods, and proposed modifications to both the total per capita cost and MSPB measures (84 FR 40754 through 40759). Additionally, we summarized all new and existing measures that would be included in the cost performance category starting with the CY 2020 performance period (84 FR 40761 through 40762). We stated that some modifications to measures used in the cost performance category might incorporate changes that would not substantively change the measure. Examples of such non-substantive changes may include updated diagnosis or procedure codes or risk adjustors. While we address such changes on a case-by-case basis, we stated that we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. However, as described in section 3 of the Blueprint for the CMS Measures Management System Version 15 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), if substantive changes to these measures that are owned and developed by CMS become necessary, we expect to follow the pre-rulemaking process for new measures, including resubmission to the Measures Under Consideration (MUC) list and consideration by the MAP. The MAP provides an additional opportunity for an interdisciplinary group of stakeholders to provide feedback on whether they believe the measures under consideration are applicable to clinicians and complement program-specific statutory and regulatory requirements. Through its Measure Selection Criteria, the MAP focuses on selecting high-quality measures that address the NQF's three aims of better care, healthy people/communities, and affordable care, as well as fill critical measure gaps and increase alignment among programs.

In section III.K.3.c.(2)(b)(v)(A) of the CY 2020 PFS proposed rule, we summarized the timeline for measure development, including stakeholder engagement activities that are undertaken by the measure development contractor, which include a technical expert panel (TEP), clinical subcommittees, field testing, and education and outreach activities (84 FR 40756).

(ii) Attribution

In this section of this final rule, we discuss our approach to the attribution methodology for cost measures along with revisions to our existing cost measures. In the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169), we adopted an attribution methodology for the total per capita cost measure under which beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries used in the Shared Savings Program. We codified this policy under § 414.1350(b)(2) in the CY 2019 PFS final rule (83 FR 59774). In the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77176), we also adopted an attribution methodology for the MSPB measure under which an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period. We codified this policy under § 414.1350(b)(3) in the CY 2019 PFS final rule (83 FR 59775).

In the CY 2019 PFS final rule (83 FR 59775), we established at § 414.1350(b)(6) that for acute inpatient medical condition episode-based measures, an episode is attributed to each MIPS eligible clinician who bills inpatient E/M claim lines during a

trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E/M claim lines in that hospitalization, and at § 414.1350(b)(7) that for procedural episode-based measures, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

As discussed in section III.K.3.c.(2)(b)(v) of the CY 2020 PFS proposed rule, we have reevaluated the total per capita cost and MSPB measures (84 FR 40756 through 40759). In the process of evaluating these measures, the TEP identified areas for potential refinement within the attribution methodology, and the revised measures that we proposed included substantial changes to the attribution methodology. As we explained in section III.K.3.c.(2)(b)(v) of the proposed rule, we believe these new attribution methodologies better establish the relationship between the clinician and the patients. In general, for the cost performance category, we stated in the CY 2020 PFS proposed rule (84 FR 40753 through 40754) that we believe that attribution is a fundamental element of the measures, and we do not believe that a cost measure can be separated from its attribution methodology. Although in prior rulemaking, we have discussed the attribution methodologies for the cost measures in the preamble and included those methodologies in the regulation text, we stated that we intend to take a different approach going forward and address attribution as part of the measure logic and specifications. We stated that for this rulemaking and in future rulemaking, we will include the attribution methodology for each cost performance category measure in the measure specifications, which were available for review and public comment at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html* during the public comment period for the proposed rule, and will be available in final form at *https://qpp.cms.gov/about/resource-library* after this final rule is published. We stated that we believe this approach is preferable because it would reduce complexity for MIPS eligible clinicians and other stakeholders by presenting the attribution methodology with the rest of the cost measure specifications, ensure non-substantive changes can be implemented without undertaking rulemaking, and align with the approach taken for measures in the quality performance category. Therefore, we proposed to revise § 414.1350(b)(2), (3), (6), and (7) to reflect that these previously finalized attribution methods apply for the 2017 through 2019 performance periods (84 FR 40754). We also proposed to establish at § 414.1350(b)(8) that beginning with the 2020 performance period, each cost measure would be attributed according to the measure specifications for the applicable performance period (84 FR 40754).

In the CY 2017 Quality Payment Program final rule, we established a final policy to attribute cost measures at the TIN/NPI level, regardless of whether a clinician's performance for purposes of MIPS is assessed as an individual (the TIN/NPI level) or as part of a group (the TIN level) (81 FR 77175 through 77176). We codified this policy under § 414.1350(b)(1) in the CY 2019 PFS final rule (83 FR 59774 through 59775). Similar to the attribution methodology for cost measures, we stated in the CY 2020 PFS proposed rule (84 FR 40754) that we also believe that the level of attribution (TIN/NPI or TIN) is best addressed as part of the measure specifications, allowing for different considerations for group and individual attribution based on the underlying measure specification. We stated that for this rulemaking and in future rulemaking, we will include the level of attribution for each cost performance category measure in the measure specifications, which will be publicly available as described in the preceding paragraph. The measure specification documents will provide the methodology for assigning attribution to an individual clinician or a group, which will align with whether the participant is reporting data as an individual clinician or a group under the MIPS program. Therefore, we proposed to revise § 414.1350(b)(1) to reflect that the current policy of attributing cost measures at the TIN/NPI level, regardless of whether a clinician's performance for purposes of MIPS is assessed as an individual or a group, applies for the 2017 through 2019 performance periods (84 FR 40753). We stated that we intend for the new regulation text proposed at § 414.1350(b)(8) also to include the level of attribution (individual clinician or group), so we did not propose additional regulation text. In section III.K.3.c.(2)(b)(vi)(B) of the proposed rule, we proposed to limit the assessment of certain cost measures to MIPS eligible clinicians who report as a group based on our assessment of the reliability of the measure at the group and individual level (84 FR 40760). Although this is not directly related to attribution, it does limit the assessment of certain measures for MIPS eligible clinicians who report as individuals.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to include the attribution methodology for each cost performance category measure in the measure specifications for this and all future proposed rules.

Response: We thank the commenters for their support.

Comment: One commenter stated that they are concerned with how proposed changes to attribution methodology will be made available to the public. The commenter suggested that this could increase complexity and make it difficult for the public to identify the changes.

Response: We disagree with the commenter and believe this change would reduce complexity for MIPS eligible clinicians and other stakeholders by presenting the attribution methodology comprehensively along with the rest of the cost measure specifications.

After consideration of the public comments, we are finalizing our proposal to revise § 414.1350(b)(2), (3), (6), and (7) to reflect that the previously finalized attribution methods apply for the 2017 through 2019 performance periods. We are also finalizing our proposal to establish at § 414.1350(b)(8) that beginning with the 2020 performance period, each cost measure will be attributed according to the measure specifications for the applicable performance period. Lastly, we are finalizing our proposal to revise § 414.1350(b)(1) to reflect that the current policy of attributing cost measures at the TIN/NPI level, regardless of whether a clinician's performance for purposes of MIPS is assessed as an individual or a group, applies for the 2017 through 2019 performance periods.

(iii) Episode-Based Measures for the 2020 and Future Performance Periods

In this section of the final rule, we discuss our proposal to add 10 newly developed episode-based measures to the cost performance category beginning with the 2020 performance period. We developed episode-based measures to represent the cost to Medicare and beneficiaries for the items and services furnished during an episode of care (''episode''). Episode-based measures are developed to compare clinicians on the basis of the cost of the care clinically related to their initial treatment of a

patient and provided during the episode's timeframe. Specifically, we define cost based on the allowed amounts on Medicare claims, which includes both Medicare payments and beneficiary deductible and coinsurance amounts. We refer our readers to the CY 2019 PFS final rule for more detail on episode-based measures and how they are established (83 FR 59767).

Prior to presenting our cost measures to the MAP for consideration, the measure development contractor has continued to seek extensive stakeholder feedback on the development of episode-based measures, building on the processes outlined in the CY 2018 PFS final rule (82 FR 53644). For more information, we refer readers to the discussion in the CY 2020 PFS proposed rule (84 FR 40754 through 40755). Further detail can also be found in the Measure Development Process document at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-measure-development-process.pdf,* which includes a discussion of the detailed clinical input obtained at each step, and details about the components of episode-based measures.

We provided an initial opportunity for clinicians to review their performance under the new episode-based measures via national field testing conducted in fall of 2018. During field testing, we sought feedback from stakeholders on the draft measure specifications, feedback report format, and supplemental documentation through an online form, and we received 67 responses, including 25 comment letters. The measure development contractor shared the feedback on the draft measure specifications with the measure-specific workgroups, who considered it in providing input on further refinements after the end of field testing. A field testing feedback summary report, which details post-field testing refinements added based on the input from the measure-workgroups, is publicly available on the MACRA Feedback Page (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html*).

Similar to previous years, we continued to engage clinicians and stakeholders, conducting extensive outreach activities. These activities included general informational email blasts, targeted email outreach to specialty societies, hosting office hours to gather input on additional opportunities for participation and outreach, and hosting the MACRA Cost Measures Field Testing Webinar to provide information about the measure development process and field test reports and a forum for stakeholder questions to ask questions.

Following the successful field testing and review through the MAP process, we proposed to add the 10 episode-based measures listed in Table 44 as cost measures for the 2020 performance period and future performance periods (84 FR 40754).

The detailed specifications for these 10 episode-based measures are available on the MACRA Feedback page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). These specifications documents consist of: (1) Methodology for constructing each measure; and (2) measure codes list file with medical codes and clinical logic. First, the methodology document provides an overview of the measure, including a description of the measure numerator and denominator, the patient cohort, and the care settings in which the measure is assessed. In addition, the document includes two one-page, high-level overviews of (1) methodology and (2) clinical logic and service codes, which were added in response to stakeholder feedback regarding provision of documentation with varying levels of detail to ensure the information is accessible to all stakeholders. The methodology document provides detailed descriptions of each logic step involved in constructing the episode groups and calculating the cost measure. Second, the measure codes list file contains the service codes and clinical logic used in the methodology, including the episode triggers, exclusions, episode sub-groups, assigned items and services, and risk adjustors. More information about the attribution methodology for each measure is available in section A.2 of the methodology documentation.

TABLE 44: Episode-Based Measures Proposed for the 2020 Performance Period and Future Performance Periods

Measure Topic	Episode Measure Type
Acute Kidney Injury Requiring New Inpatient Dialysis	Procedural
Elective Primary Hip Arthroplasty	Procedural
Femoral or Inguinal Hernia Repair	Procedural
Hemodialysis Access Creation	Procedural
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	Acute inpatient medical condition
Lower Gastrointestinal Hemorrhage*	Acute inpatient medical condition
Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels	Procedural
Lumpectomy Partial Mastectomy, Simple Mastectomy	Procedural
Non-Emergent Coronary Artery Bypass Graft (CABG)	Procedural
Renal or Ureteral Stone Surgical Treatment	Procedural

*This measure was proposed only for groups. Please reference section III.K.3.c.(2)(b)(vi)(B) of this final rule.

The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal to adopt the 10 episode-based measures under the cost performance category for the 2020 MIPS performance period and future performance periods.

Response: We appreciate the support of the commenters.

Comment: A few commenters expressed concern regarding the measure development process including the perceived lack of transparency in the process, the measure development timeline, and the reliance on administrative claims data for measure calculations. Some commenters expressed concern that the field-testing process for episode-based measures was inadequate and suggested a delay to allow clinicians more time to better understand the measures before they are used to determine cost performance category scores. One commenter recommended that CMS work with specialty societies throughout the maintenance process to ensure continuous input from the provider community. Another commenter appreciated that CMS provided feedback reports to clinicians who were attributed to episode-based measures during field testing. However, only a few clinicians could access the feedback reports to provide further input.

Response: We aim to be open and transparent in every stage of the measure development process. The measure development process collects input at every step of development, including prioritizing episodes for measure development, for which our measure development contractor convened over 260 clinician experts across 10 Clinical Subcommittees. The measure development contractor subsequently convened 11 workgroups and over 130 clinician experts to obtain detailed clinical input on each aspect of the measures' specifications. For each meeting of these panels, the measure development contractor provided extensive analyses to inform the workgroup members' recommendations. This process, which began in April 2018 and concluded in January 2019, is discussed in detail in CY 2020 PFS proposed rule (84 FR 40754). The measure development process has also been refined based on stakeholder input received. For example, smaller, more focused measure-specific expert workgroups were added to develop the 10 new episode-based measures based on feedback the measure development contractor obtained from members of the first wave of clinical subcommittees. Additionally, as requested by stakeholders, the measure development contractor offered a listen-only observer dial-in line for stakeholders during the Wave 3 measure-specific workgroup meetings convened in August 2019. We recognize stakeholders' requests for an extended development timeline to allow more opportunities for clinicians to provide input on the measures and will consider this feedback for future waves of measure development.

We are committed to continuing to increase awareness about the measures both during field testing and through other education and outreach activities. During field testing, we provided extensive materials regarding the measures, including measure specifications, an FAQ document, a fact sheet, testing results, and mock reports for clinicians who did not receive a field test report. Additionally, we hosted webinars to provide information on the measures under field testing, one during the field testing period and another after field testing to provide an update on the measure refinements that resulted from field testing feedback. We have also posted additional documentation on the MACRA feedback page such as the measure justification forms, which provide more testing information for the measures. Given the extensive outreach we have conducted, as well as the education materials we have posted for these measures, we believe they are ready for implementation. We will continue to welcome feedback on how the field testing period and the development process can be further refined to increase awareness about the measures.

Section 1848(r)(5) of the Act requires the Secretary, as the Secretary determines appropriate, to use certain claims data to conduct an analysis of resource use. We believe that an advantage of using claims data is that it creates no additional reporting burden for clinicians, which greatly increases the feasibility of calculating and reporting cost measures. We will continue to consider incorporating additional data sources in measure calculations and welcome feedback on potential alternatives.

Comment: Some commenters expressed concern about a lack of alignment between cost and quality measures, stating as an example that the Screening/Surveillance Colonoscopy episode-based measure was finalized as the quality measure, Screening Colonoscopy Adenoma Detection Rate (Measure 343), was removed from the MIPS quality performance category. These commenters expressed concern that this would cause clinicians to focus on costs and not on quality. One commenter recommended that CMS complete an empiric validity test to demonstrate how each of these measures correlates to quality measures reported within MIPS.

Response: As discussed in the CY 2020 PFS proposed rule (84 FR 40732 through 40745), we are focused on moving the MIPS program forward with an aligned set of measures and activities known as an MVP. In the course of implementing the framework for MVPs, we will consider the relationship between cost and quality. We agree with the importance of cost and quality alignment, and view it as an essential component of episode-based measures. For instance, as part of episode group prioritization for development, the measure development contractor asked clinical subcommittee members to consider the measures' potential for alignment with established quality measures. This includes consideration of whether there is potential for overlap in covering the same patient cohort and the dimensions of care that the quality measure would be capturing in relation to a procedure or condition that the episode-based cost measure could focus on. We are also considering these comments on the quality measures retained and removed within the MIPS program in more detail in section III.K.3.c.(1)(d) of this final rule.

Comment: Some commenters expressed concern that the episode-based measures proposed for inclusion in CY 2020 performance period and future years had not been endorsed by the NQF. One commenter recommended that all measures included in the MIPS program be endorsed by NQF.

Response: We intend to submit the episode-based measures for NQF endorsement in a future endorsement cycle; however, NQF endorsement is not a requirement for implementing cost measures in MIPS. The MAP reviewed the episode-based measures and provided the recommendation of ''conditional support for rulemaking'' with the condition that the measures be submitted for NQF endorsement. This review provided stakeholders with additional public comment opportunities, which the MAP considered along with submission materials regarding the reliability and validity of the measures. In addition, we provided testing results that examined the measures' scientific acceptability in the measure justification forms, which are available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). The measures have undergone a comprehensive stakeholder input process and extensive testing, and we believe they are ready for implementation.

Comment: Some commenters suggested the inclusion of social risk factors such as sociodemographic status when risk adjusting the proposed

episode-based measures. Some of these commenters expressed concern that risk adjustment for the episode-based measures uses only variables included in the CMS–HCC risk adjustment model and other clinical characteristics, and they suggest that CMS explore alternative risk adjustment data to include. One commenter recommended that CMS not utilize claims data for risk adjustment.

Response: Each measure's risk adjustment model employs a common starting point of the CMS–HCC model, but the measure-specific expert workgroups considered enhancements to the model through the addition of risk factors specifically adapted for each episode group. The measure development contractor provided empirical analyses stratifying patient (or episode) cohorts of interest to inform the workgroup members' considerations of how particular factors should be accounted for in each measure's risk adjustment model. Workgroup members also considered patient characteristics, factors outside of the influence of the attributed clinicians, or any other measure-specific factors that would help prevent unintended consequences.

We are aware of the concern regarding risk adjustment for social risk factors and are continuing to consider options to account for social risk factors that would allow clinicians to view disparities that would potentially incentivize improvement in care for beneficiaries. We remain concerned about holding clinicians to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities. As part of the standard development and testing process, the measure development contractor conducted analyses to assess the impact of the following social risk factors: Income; education; population; employment; race; sex; and dual-eligibility status, which can be found in the measure justification forms for the episode-based measures available for download from the MACRA Feedback Page. Results of these analyses found very little to no effect on the predictive power of the risk adjustment models used when variables for social risk factors were included in the models, compared to using the current models. More information on these analyses is available in the measure justification forms posted on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). We will continue to monitor the potential effect of social risk factors on episode-based measures implemented in MIPS on an ongoing basis.

Regarding the use of claims data for risk adjustment, section 1848(r)(5) of the Act requires the Secretary, as the Secretary determines appropriate, to use certain claims data to conduct an analysis of resource use. As we stated in a prior response, we believe that an advantage of using claims data is that it creates no additional reporting burden for clinicians, which greatly increases the feasibility of calculating and reporting cost measures. We will continue to consider incorporating additional data sources in risk adjustment and welcome feedback on potential alternatives.

Comment: Some commenters expressed concerns regarding the perceived issue of double counting costs assigned to the revised total per capita cost and MSPB clinician measures and the episode-based measures. For example, commenters were concerned that costs may be double counted when clinicians are measured by more than one type of measure (that is, being measured by the MSPB clinician measure and an episode-based measure that have different frameworks, benchmarks, and comparison groups).

Response: We understand the concern about double counting of costs to be a concern about the potential for a particularly costly service, episode, or patient to have an outsized effect on a clinician's cost measure performance as services can be included in more than one measure score calculation. We believe that the construction and calculation of the cost measures in fact guards against this possibility.

Any given service and its associated cost is only included once per episode per attributed clinician for a given measure. Each measure then calculates the average observed to expected cost across episodes for an attributed clinician to generate a score for that particular measure. Each cost measure is calculated separately, and then averaged into a single score for the MIPS cost performance category. In the aggregation of a MIPS cost performance category score, the relative impact of a high or low cost service in each cost measure is averaged for a given clinician or clinician group, rather than simply counted twice. That is, calculation of the cost performance category score as an average of individual cost measure scores avoids compounding good or poor results, which would otherwise occur if the score was calculated as a simple addition of cost measure scores. This ensures that clinicians will not be double-penalized or rewarded for a high or low cost service.

In addition, this approach allows each measure to capture clinician performance within the intent and scope of each individual measure. Episode-based measures only include costs related to the episode for a clinical condition or procedure and are focused on the clinician's specific role; in comparison, population-based measures include all services that are provided to a patient over a given timeframe to focus on a broader range of patient care. Specifically, the MSPB clinician measure assesses the cost performance of clinicians providing care at inpatient hospitals, while the total per capita cost measure focuses on primary care management outside the inpatient setting. By design, some costs for a patient may be included in more than one measure. For example, a patient with a primary care clinician who is providing overall care may be admitted to hospital to undergo a planned surgical procedure, which is performed by a surgeon. The TPCC measure assesses the primary care clinician's overall care for the patient, and the MSPB clinician measure evaluates the surgeon's inpatient care of the patient. By having the primary care clinician's responsibility ongoing before, during, and after the inpatient stay, the TPCC measure captures the nature of primary care. Similarly, by covering the surgeon who performs the procedure in the hospital, the MSPB clinician measure assesses the care before, during, and after the inpatient stay. Holding both the primary care clinician and surgeon responsible for the patient during the inpatient stay helps to align incentives across care settings through the patient care continuum, which encourages care coordination. To do otherwise may leave a gap in accountability, limiting the extent to which cost measures can operate together to encourage care coordination for improved patient outcomes.

Comment: We received one comment stating that they were unable to review the measure specifications at the link provided.

Response: We had posted the measure specifications at the link specified in the proposed rule for the duration of the public comment period, and we have reposted the specifications (updated to reflect the policies we are finalizing in this rule) on the MACRA Feedback page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). We expect to post the measure specifications in final form in

the Quality Payment Program resource library (*https://qpp.cms.gov/about/resource-library*) by the end of the year.

Comment: A few commenters urged CMS to better educate clinicians to ensure that they understand how to interpret the measure specifications and feedback report data. One commenter urged CMS to ensure that cost measures are actionable by making episode-based cost measure field testing reports available after the testing period concludes. Some commenters urged CMS to provide real time feedback early in the year when new measures are used or calculate data for new measures using historical data for clinicians to better understand their performance and benchmark. A few commenters recommended that feedback reports provide more detailed information including demographic and clinical characteristics for attributed beneficiaries.

Response: We will continue to work to increase familiarity with the measures through education and outreach activities. We produced various education and outreach materials during field testing, including measure specifications, an FAQ, fact sheet, testing results, and mock reports for clinicians who did not receive field test reports with performance feedback. In addition, we hosted a webinar, where we provided an overview of the field test reports and answered questions from stakeholders. Throughout the field testing period, we provided helpdesk support regarding field testing and the reports through the Quality Payment Program Service Center. Lastly, we convened office hours sessions with specialty societies to help coordinate targeted outreach and ensure that we reached clinicians who were most likely to be attributed the measures. We recognize the importance of education and outreach, and expect to continue these types of activities in future field testing periods.

The field test reports from the fall 2018 field testing were available for review through for a period after the field testing period concluded and were removed once the portal was decommissioned. We are exploring alternative venues to facilitate access to the field test reports for future field testing. In this process, we will also consider ways the reports can be made available after the field testing period concludes.

We appreciate the feedback regarding the availability of real time feedback early in the year. We note that the nature of claims-based measures presents additional considerations that affect the availability of real time feedback. We allow at least a 60-day run out to allow for adjustments to claims and ensure data completeness. This, along with episode length for the cost measures must be accounted for in considerations of providing real time feedback early in the beginning of the performance year. We will continue to explore ways to extend accessibility of materials such as the field test reports, to increase access to information about clinicians' expected performance. We will also continue to consider ways to offer actionable data and feedback on cost measures to clinicians in the future, including the format of reports and the information they contain.

Comment: A few commenters supported the development and inclusion of episode-based measures but expressed concern that measures for their particular specialty or focus area, such as anesthesia, dermatology, chronic conditions and plastic surgery were not yet included. One commenter recommended that all measures to be fully vetted by clinicians to ensure their clinician relevance. A few commenters recommended that CMS accelerate and establish a process for the development of additional episode-based measures in order to ensure fair comparisons and reliability.

Response: We continue to work to develop new episode-based measures that could be considered for inclusion in the cost performance category in future years. We expect that future measures may apply to a greater range of specialties and clinical areas, including areas suggested by commenters. In fact, episode-based measures focusing on chronic conditions and dermatology are currently being developed as part of Wave 3 of measure development. We expect these measures to undergo field testing next year. More information regarding Wave 3 measures is available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). We anticipate the development of additional waves of episode-based cost measures in the future that will expand the range of specialties and clinical areas included.

Section 1848(r)(2)(D)(i)(I) of the Act requires us to establish care episode groups and patient condition groups, which account for a target of an estimated one half of expenditures under parts A and B with such target increasing over time as appropriate. The measure development process includes a data-driven expert input process that is critical to the development of robust, meaningful, and actionable episode-based measures, though it presents a trade-off between the number of measures we can develop and the level of clinician and expert input we can involve in this process. We aim to find the right balance to ensure the addition of meaningful episode-based measures, while still undergoing this comprehensive clinician-input driven process. While the development of more episode-based measures does increase the number of clinicians covered by the measures, it does not ensure fair comparisons and greater reliability. To ensure fair comparisons and greater reliability, we pair our extensive stakeholder input process with robust testing to ensure that the measures are clinically relevant and measure clinicians fairly and reliably. Information about measure testing is available in the National Summary Data Report and the measure justification forms, which are available on the MACRA feedback page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*).

Comment: A few commenters generally opposed the inclusion of episode-based measures. Some commenters recommended that CMS not include the proposed and newly developed episode-based measures until they can be further evaluated and better understand the implications on impacted clinicians. For example, CMS should consider whether episode-based measures would create an unfair playing field amongst specialist and subspecialists. One commenter recommended that CMS adopt additional episode-based measures only in efforts to collect data to inform the development of MVPs.

Response: We conducted extensive field testing activities in the Fall of 2018 to provide clinicians with an opportunity to gain experience with and evaluate their performance on the episode-based measures that were field tested. We have also performed testing on the measures, including reliability and validity testing. The details of the testing are available in the measure justification forms and National Summary Data Report posted on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). The measures were also developed with extensive clinician and expert input to inform each aspect of the measure specifications. We believe that

the episode-based measures are ready for use in the program given the testing we have conducted and the extensive involvement of clinician experts in the development of the measures. We will also continue to develop new episode-based measures to cover a wider range of specialties that are not currently measured by the episode-based or population-based measures.

We continue to work to develop new episode-based measures that could be considered for inclusion in the cost performance category in future years and appreciate the input about how to more closely link the development of episode-based measures and MVPs. We do note that while episode-based cost measures may be helpful for understanding the use of MVPs, these measures use Medicare claims data, so it is not necessary to adopt additional measures in order to collect data.

As we develop additional cost measures, we aim to measure as many clinicians as possible in the cost performance category. We recognize that due to the current nature of measurement that some clinicians will be measured on more cost measures than others, while others will not be measured on cost at all. We believe that the principles of fairness espoused by the commenter can be supported by measuring clinicians using the best measures or activities in each performance category. However, we disagree that the episode-based measures would present an unfair playing field between specialists and subspecialists. Clinicians attributed under these measures are compared to peers who are similarly attributed. Clinicians who are not measured on the episode-based measures are potentially measured on the other cost performance category measures and similarly compared to their peers when assessing cost performance. We will continue to evaluate our scoring policies to ensure that scores reflect performance and not the practice specialty or type of a clinician or group.

Comment: Some commenters expressed concern with certain specifications for the Hemodialysis Access Creation episode-based measure. These commenters expressed concern that the surgeon that performs the trigger procedure is not generally responsible for follow-up management but would be held accountable under this measure. They also expressed concern that the measure did not differentiate between patients receiving the procedure for the first time or those who had the procedure previously. They also indicated that patients receiving this procedure were complex with multiple illnesses and that it would be difficult to differentiate services associated with hemodialysis from other services and to apply risk adjustment to this measure. One commenter suggested a change to the technical specifications of the measure to exclude patients who die within 90 days of the close of the episode. Another commenter recommended that the inclusion and exclusion criteria for this cost measure should include a clean, pre-trigger period of 12 months where the patient is not identified on a claim with a billing code for outpatient dialysis.

Response: The measure was developed with expert clinical input from the workgroup to ensure that only costs of care within the reasonable influence of the attributed clinician for the defined patient population are included. Exclusions identify patient characteristics and factors in the patient's medical history that might adversely affect the patient's treatment during the episode, to an extent that is outside the influence of the managing clinician. As such, we do not believe that it is appropriate to retroactively exclude patients who die within 90 days after the close of the episode if they would otherwise fit in with a homogenous patient cohort captured by the measure. This is consistent with the measure framework for the episode-based measures.

The measure's risk adjustment model includes variables specific to the measure that recommended by the workgroup, in addition to those in the CMS–HCC model, that address issues of patient complexity and comorbidities. The model risk adjusts for the presence of previous procedures to account for patients undergoing multiple vascular access procedures, and adjusts for patients who undergo two-stage procedures.

Lastly, including only pre-dialysis patients with an extended clean period, as suggested, excludes a very large portion of the patient population this measure aims to capture. We are concerned that this change may also incentivize clinicians to wait until a patient is on dialysis before placing a vascular access to avoid being attributed episodes. Delaying the placement of a suitable vascular access could negatively impact patient health outcomes and further increase the number of dialysis patients that begin treatment with a catheter. We are finalizing the Hemodialysis Access Creation measure as proposed.

Comment: One commenter indicated that there are facilities such as academic medical centers and tertiary medical centers who may have disproportionately complex patients, which may result in higher costs within episodes. Hence, as result of cost measures including transfers and emergent cases, it would be inappropriate to compare the efficiency of these episodes among hospitals who do not have a similar complex patient population.

Response: We recognize that complex patients may be costlier to treat, and the episode-based measures include robust statistical techniques to ensure that differences in the patient population are appropriately accounted for. Through risk adjustment, the measures are adjusted for factors outside of the clinician's control that can influence spending such as the care setting and patient characteristics to achieve a fair comparison of cost across clinicians. Risk adjustment aims to isolate the variation in clinicians' costs to Medicare to those costs that clinicians can reasonably influence. Accounting for these factors is one way to ensure the validity of cost measures and mitigate potential unintended consequences. Additionally, the creation of strictly defined episodes produces more homogeneous populations within each episode group that allows for more accurate comparisons of clinician performance.

Comment: A commenter expressed concern that the measure exclusion list for the Inpatient COPD Exacerbation episode-based measure does not adequately capture patients who have undergone lung surgery/resection and should be excluded from this measure, and provided additional codes for CMS to consider adding to the list of codes used to capture patients who should be excluded due to history of lung resection.

Response: Patients who have undergone lung surgery/resection are excluded in the Inpatient COPD Exacerbation measure; however, we agree that the additional lung resection codes suggested by the commenter would capture an additional group of lung resection patients. The addition of the suggested codes to the exclusions list is in keeping with the clinical input provided by the expert workgroup and would remove approximately 260 episodes, representing less than 0.1 percent of all episodes. As such, we are finalizing the Inpatient COPD Exacerbation measure with the exclusion list expanded to include the recommended lung resection codes, which are listed in the Inpatient COPD Exacerbation measure codes list file available for download on the MACRA Feedback Page (*https://www.cms.gov/*

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html).

Comment: One commenter expressed concern that the Non-Emergent CABG episode-based measure included the code 33406 (Replacement of the Aortic Valve Using Human Donor Valve on Heart-Lung Machine) as a trigger and not an exclusion. Additionally, the commenter also stated concerns that the stroke service assignment window of <15 days from trigger event was too long and believe <7 days would be more appropriate.

Response: We agree that the suggested exclusion of code 33406 on trigger claims is clinically reasonable and in keeping with the intention of the Non-Emergent CABG measure expert workgroup not to assign procedures or conditions that represent small sub-populations with higher and unpredictable costs. CPT code 33406 indicates a unique type of aortic valve replacement in which the aortic valve is replaced by a human valve. This procedure is typically reserved for either patients with congenital heart disease or younger patients with infection of their native valve and occurs in a very different cohort of patients than the majority of Non-Emergent CABG measure episodes. These patient-level differences likely do influence downstream post-operative recovery and costs. Other similar complicating operative factors are already excluded from the measure.

To clarify, the Non-Emergent CABG episode-based measure does not include any stroke readmissions. The measure assigns inpatient rehabilitation facility (IRF) stays secondary to stroke post-CABG. Only stroke costs in the index hospitalization and subsequent rehabilitation are included in the proposed measure. Given that many post-CABG stays complicated by stroke are longer than 7 days, we do not intend to finalize any updates to the service assignment for the Non-Emergent CABG measure.

We are finalizing the Non-Emergent CABG measure with the removal of CPT code 33406 from the list of episode triggers and addition of the code to the list of exclusions, found in the measure codes list on the MACRA Feedback page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*).

Comment: One commenter expressed concerns that CMS does not include the Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis episode-based measure for several reasons. The commenter indicated that the patient level variability in acuity/intensity of care required for the Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis episode-based measure, can make this measure a non-meaningful assessment of physician care, and has general concerns with the attribution methodology for this specific episode-based measure.

Response: The Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis measure was developed with expert clinical input to ensure that only costs of care within the reasonable influence of the attributed clinician, including nephrologists, for the defined patient population are included. In addition to risk adjustment variables in the CMS–HCC model that address issues of patient complexity and severity, the measure's risk adjustment model includes variables specific to the measure that were recommended by the workgroup to account for severity, such as variables for length of stays in the hospital or intensive care unit and recent admission to long term care facilities. Certain patient cohorts, such as those with diagnosis of end-stage renal disease (ESRD), post-discharge dialysis for ESRD, and kidney transplants are excluded from the patient population to ensure that the measure captures a homogenous population of patients. Additionally, the workgroup considered how to trigger and attribute episodes to ensure that they were clinically relevant and within a clinician's influence. An acute kidney injury episode is attributed to any clinician who bills a trigger procedure code for dialysis during the inpatient stay or to a nephrologist who bills an inpatient evaluation and management (E/M) service during the inpatient stay with hospital and critical care services accompanied by a diagnosis for acute kidney failure. This attribution methodology operationalizes the workgroup's recommendation for the measure development contractor to attribute Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis episodes to the clinicians that are most likely to treat this patient cohort and to encourage care coordination for clinicians involved in the care continuum of patients included in this measure. We are finalizing the Acute Kidney Injury (AKI) Requiring New Inpatient Dialysis measure as proposed.

Comment: A commenter expressed concerns with the current attribution methodology for episode-based measures. The commenter recommended that CMS include MIPS eligible clinicians who bill plurality of 97000 series codes during an episode. This modification would allow CMS to more accurately capture therapists within applicable episode-based measures.

Response: The episode-based measures include all costs relevant to the episode, including services provided by therapists in the 97000 series codes when appropriate for the treatment of the condition or procedure being measured. The episode-based measures are only attributed to those clinicians who either perform or assist with the procedure in question or are provide guiding care for the acute episode (for example, an orthopedist who performs a hip arthroplasty or a hospitalist that cares for a patient hospitalized for an acute exacerbation of chronic obstructive pulmonary disease). We will continue to consider how therapists that bill plurality of 97000 series codes can be included in existing and future episode-based cost measures.

After consideration of the public comments, we are finalizing our proposal to include the 10 episode-based measures listed in Table 44 in the cost performance category beginning with the 2020 MIPS performance period with the modifications discussed in our responses to comments above.

(iv) Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve the physician, practitioner, and other stakeholder communities in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from stakeholders, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed

under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other stakeholders.

In December 2016, we published the Episode-Based Measure Development for the Quality Payment Program (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Draft-list-of-episode-groups-and-trigger-codes-December-2016.zip*) and requested input on a draft list of care episode and patient condition groups and codes as required by sections 1848(r)(2)(E) and (F) of the Act. We additionally requested feedback on our overall approach to cost measure development, including several pages of specific questions on the approach for clinicians and stakeholders to provide feedback. We used this feedback to modify our cost measure development and ensure that our approach is continually informed by stakeholder feedback. As required by section 1848(r)(2)(G) of the Act, in January 2018, we posted an operational list of 8 care episode groups and patient condition groups that we refined with extensive stakeholder input, along with the codes and logic used to define these episode groups. This operational list is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-Operational-List-of-Care-Episode-and-Patient-Condition-Codes.zip.*

Under section 1848(r)(5)(A)(iii) of the Act, to evaluate the resources used to treat patients with respect to care episode and patient condition groups, the Secretary shall, as the Secretary determines appropriate, conduct an analysis of resource use with respect to care episode and patient condition groups. In accordance with this section, we used the 8 care episode groups and patient condition groups included in the operational list as the basis for the 8 episode-based measures that we developed in 2017 through early 2018 and finalized for use in MIPS in the CY 2019 PFS final rule (83 FR 59767–59773). We did not revise this operational list through rulemaking in 2018 as we did not receive stakeholder feedback requesting updates to how these episode groups are defined and there were no new developments requiring revisions. Under section 1848(r)(2)(H) of the Act, we proposed to revise the operational list beginning with CY 2020 to include 10 new care episode and patient condition groups, based on input from clinician specialty societies and other stakeholders (84 FR 40756). The 10 care episode and patient condition groups were included in the draft list that we posted in December 2016 and refined based on extensive stakeholder input as described in section III.K.3.c.(2)(b)(v)(A) of this final rule. Our revisions to the operational list beginning with CY 2020 are available on our MACRA feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html.* These care episode and patient condition groups serve as the basis for the 10 new episode-based measures that we proposed for the cost performance category in section III.K.3.c.(2)(b)(iii) of the proposed rule (84 FR 40754 through 40756) and are finalizing in Table 47 in section III.K.3.c.(2)(b)(viii) of this final rule.

While we received many comments on measures that we proposed to include in the cost performance category as discussed in section III.K.3.c.(2)(b)(iii) of this rule, we did not receive any comments specifically on our proposal to revise the operational list. After reviewing and considering the comments on the merits of the proposed measures as discussed in those sections, we are finalizing our proposed revisions to the operational list beginning with CY 2020 to include the 10 new care episode and patient condition groups.

(v) Revised Cost Measures Re-Evaluation Process for the Total Per Capita Cost and Medicare Spending Per Beneficiary Clinician Measures

For the purpose of assessing performance of MIPS eligible clinicians in the cost performance category, we finalized both the total per capita cost and MSPB measures to be included in the MIPS program in CY 2017 Quality Payment Program final rule (81 FR 77166). We proposed to modify both of these measures based on stakeholder input from prior public comment periods and recommendations from the TEP (84 FR 40756). We also proposed to modify the measure title from Medicare Spending Per Beneficiary (MSPB) to Medicare Spending Per Beneficiary clinician (MSPB clinician) to distinguish it from measures with similar names in use in other CMS programs and to improve clarity. We proposed to change the name from MSPB to MSPB clinician at §§ 414.1350(b)(3) and 414.1350(c)(2) (84 FR 40758). The measure development contractor convened the standing TEP and completed field testing to consider potential refinements to these measures, which we summarized in section III.K.3.c.(2)(b)(v)(A) of the proposed rule (84 FR 40756 through 40757).

(A) Total Per Capita Cost Measure

We finalized the total per capita cost measure for use in MIPS as an important measurement of clinician cost performance. Having been used in the Physician VM program, it had been tested and was reliable for Medicare populations and was familiar to the clinician community. When we finalized this measure for use in MIPS, we noted that as with all the cost measures, we will maintain this measure and update its specifications as appropriate (82 FR 53643). We continue to believe that the existing measure is appropriate to use in MIPS and continue to be committed to maintaining the cost measures with consideration of stakeholder input and testing. However, as a part of our routine measure maintenance, we re-evaluated the total per capita cost measure. The re-evaluation was informed by feedback received on this measure through prior public comment periods, as described in the CY 2017 (81 FR 77017 through 77018) and CY 2018 (82 FR 53577 through 53578) Quality Payment Program final rules, as well as feedback that arose in the measure development contractor's discussions with the TEP during the process of re-evaluation. This feedback is summarized below:

- The total per capita cost measure's attribution methodology assigned costs to clinicians over which the clinician has no influence, such as costs occurring before the start of the clinician-patient relationship.
- The attribution methodology did not effectively identify primary care relationships between a patient and a clinician and could potentially attribute beneficiaries to a clinician not responsible for the beneficiaries' primary care.
- The measure did not account for the shared accountability of clinicians and that attributing costs to a single clinician or clinician group could cause fragmentation of care.
- The beneficiary risk factors were determined one year prior to the start of the performance period, which will preclude the risk adjustment methodology from reflecting the more expensive treatment resulting from comorbidities and/or complications that might arise during the performance period.
- The feedback summarized above informed the four modifications that we proposed for the total per capita cost measure.

First, we proposed to change the attribution methodology to more accurately identify a beneficiary's primary care relationships (84 FR

40757). This is done by identifying a combination of services that occur within a short period and indicate the beginning of a relationship. More specifically, a primary care relationship is identified by a candidate event, defined as the occurrence of an E/M service such as an established patient assisted living visit or an outpatient visit (that is, the E/M primary care service), paired with one or more additional services indicative of general primary care (for example, routine chest X-ray, electrocardiogram, or a second E/M service provided at a later date). The candidate event initiates a year-long risk window from the E/M primary care service. The risk window is the period during which a clinician or clinician group could reasonably be held responsible for the beneficiary's treatment costs, and the initiation of the risk window at the onset of the candidate event ensures that costs are attributed only after the start of the clinician-patient relationship. Only the portion of the risk window that overlaps with the performance period, which is divided into 13, 4-week blocks called beneficiary-months, is attributable to a clinician for a given performance period. For example, if the risk window were initiated during one MIPS performance period and ends in the following MIPS performance period, only the beneficiary-months that occur during the earlier MIPS performance period will be attributed to the clinician/clinician group to calculate the measure for that particular MIPS performance period. Dividing the performance period into beneficiary-months allows costs to be assigned to clinicians and clinician groups during the parts of the year they are primarily responsible for the patient's care management.

With this methodology, it is possible for multiple candidate events to occur between a clinician and beneficiary over time, and an additional candidate event occurring during an existing risk window reaffirms and extends the period of the clinician's responsibility. For example, if 2 candidate events for the same clinician and the same beneficiary occur 6 months apart, a separate 12-month risk window initiates from the start of each of these candidate events, and the clinician may be attributed beneficiary-months spanning 18 months and 2 different performance periods. As we described above, for risk windows that span multiple performance periods, only the beneficiary-months contained within a given performance period are used to calculate the measure for that performance period. Beneficiary-months that overlap between the 2 risk windows are collapsed to ensure that costs are only accounted for once. Furthermore, if different clinician groups initiated these 2 risk windows for the same beneficiary, the risk windows will occur concurrently and will be attributed to their respective TINs. Within an attributed TIN, only the clinician with the TIN/NPI combination performing the highest number of candidate events is attributed the beneficiary-months, since this TIN/NPI combination is deemed to have the most substantive relationship with the beneficiary. Finally, multiple TINs and TIN/NPIs billing under different TINs may be attributed beneficiary-months for the same beneficiary during the performance period. This attribution method allows multiple clinicians to be considered for the provision of ongoing primary care for a patient, which accounts for changes in primary care relationships (for example, for beneficiaries who move during the year) and reflects shared clinical responsibility for a patient's care.

To illustrate how candidate events identify primary care relationships, we provided an example of a clinical scenario in which physicians in the primary care medical practice see a beneficiary as part of the beneficiary's routine health maintenance (84 FR 40757 through 84 FR 40758). A beneficiary is feeling unwell and goes to a medical practice. At the practice, the beneficiary sees a family practice clinician who provides an E/M service (one that has been identified as related to primary care) for routine health maintenance. The clinician prescribes a course of medication as part of the care plan. The beneficiary returns to the same practice 2 months later when she notices new symptoms. At this visit, she sees a different family practice clinician who examines her, adjusts her care plan, and asks her to return in 3 months for a follow-up in case diagnostic testing or a change in medication is required. These two E/M services that occur within proximity (that is, the initial E/M service and the paired event 2 months later—a second E/M service) constitute the candidate event and indicate that a primary care relationship has begun from the time of the first visit to the medical practice. The first E/M service (identified as related to primary care) opens a one-year period (or risk window) from the date of the service. This is illustrated graphically in section 2.0 of the measure specifications available on the MACRA Feedback page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA–MIPS-and-APMs/MACRA-Feedback.html*). During the risk window, the attributed clinician/clinician group can be held responsible for the overall costs of care for that beneficiary. The TIN for the medical practice will be attributed the beneficiary and the TIN/NPI within this practice that provides the most primary care E/M services that initiate candidate events will be attributed the beneficiary. Under the current total per capita cost measure, the TIN and TIN/NPI will have been attributed this beneficiary from the beginning of the calendar year and held accountable for services the beneficiary might have received before her first visit to the medical practice.

Second, we proposed to change the attribution methodology to more accurately identify clinicians who provide primary care services, by the addition of service category exclusions and specialty exclusions (84 FR 40758). Specifically, candidate events are excluded if they are performed by clinicians who: (1) Frequently perform non-primary care services (for example, global surgery, chemotherapy, anesthesia, radiation therapy); or (2) are in specialties unlikely to be responsible for providing primary care to a beneficiary (for example, podiatry, dermatology, optometry, ophthalmology). As a result of these exclusions, clinician specialties considered for attribution are only those primarily responsible for providing primary care, such as primary care specialties and internal medicine subspecialties that frequently manage patients with chronic conditions that are in their area(s) of expertise. We did not propose to change the adjustment for specialty; as such, the measure will continue to adjust for specialty to account for variation in cost across clinician specialties and in clinician groups with diverse specialty compositions.

Third, we proposed to change the risk adjustment methodology to determine a beneficiary's risk score for each beneficiary-month using diagnostic data from the year prior to that month rather than calculating one risk score for the entire performance period using diagnostic data from the previous year (84 FR 40758). This methodology will better account for any changes in the health status of the beneficiary for the duration of a primary care relationship and during the performance period. In addition, we proposed to add an institutional risk model to improve risk adjustment for clinicians treating institutionalized beneficiaries.

Fourth, we proposed to change the measure to evaluate beneficiaries' costs on a monthly basis rather than an annual basis (84 FR 40758). Specifically, the performance period during which costs are assessed is divided into 13 beneficiary-months, mentioned earlier, allowing for the measure and the risk adjustment model to reflect changes in patient health characteristics at any point throughout the performance period. In addition, this refinement will avoid measuring annualized costs for beneficiaries whose death date occurs during the performance period, which could potentially disincentivize care for older and sicker patients.

Further detail about these changes to the measure, as well as a comparison to the total per capita cost measure as currently specified, is available in the measure specifications documents available on the MACRA Feedback page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*).

The revised total per capita cost measure underwent MAP review during the 2018–2019 cycle. In December 2018, the MAP Clinician Workgroup gave the preliminary recommendation of ''conditional support for rulemaking,'' with the condition of NQF endorsement. In January 2019, the MAP Coordinating Committee reversed the Clinician Workgroup's preliminary recommendation and provided a final recommendation of ''do not support for rulemaking with potential for mitigation''. More detail on the mitigating factors is available in the MAP's final report at *http://www.qualityforum.org/Publications/2019/03/MAP_Clinicians_2019_Considerations_for_Implementing_Measures_Final_Report.aspx.*

In the CY 2020 PFS proposed rule (*84 FR 40758*), we stated that we believe that the revised measure provides a more appropriate and valid attribution approach. We considered the option of proposing to remove the current version of the measure from the program and not proposing to replace it with a revised version. However, because we have developed and implemented only a handful of episode-based measures at this time, a substantial proportion of clinicians would be left with only the MSPB clinician measure for the cost performance category. Because fewer than half of all clinicians in MIPS meet the case minimum for the MSPB clinician measure, and no other measure addresses the costs of primary care, we stated that we believe it is appropriate to use the best version of the total per capita cost measure available to us. While we recognize and value the MAP's expressed concerns regarding the revised measure specifications, we stated that we believe that we have adequately addressed the mitigating factors through the information we have made publicly available (including testing results in the measure justification forms available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html*), as well as our discussions with stakeholders at the MAP and through further education and outreach activities. Thus, we proposed to include the total per capita cost measure with these revised specifications in the cost performance category beginning with the CY 2020 performance period (84 FR 40757).

The following is a summary of the comments we received and our responses.

Comment: Some commenters supported the proposed changes to the total per capita cost measure and the proposed changes in attribution, particularly the exclusion of certain clinicians from attribution based on the services provided.

Response: We thank the commenters for their support.

Comment: Many commenters opposed the inclusion of the revised total per capita cost measure, suggesting that broad measures of costs should not be included in a clinician program. Some commenters indicated that the proposed changes would not address their fundamental disagreement, particularly with attribution and reliability, by including the measure. Rather, some commenters believe that condition- or specialty-specific measures more effectively gauge the costs that clinicians are able to influence. Other commenters recommended that only episode-based measures be included in the cost performance category. Some commenters indicated that the MAP had recommended against including the revised total per capita cost measure in the MIPS program because of multiple concerns related to attribution and actionability. Some commenters expressed concern about including a broad measure of costs of care without including a comparable quality measure.

Response: We continue to believe that the total per capita cost measure provides an important measurement of clinician cost performance (82 FR 53644) and that the measure intent to capture broad, overall care plays a significant role in MIPS to complement the more granular information captured by episode-based measures. By including both episode- and population-based measures in the cost performance category, we are able to capture more aspects of care and ensure that there is continuity in clinician incentives throughout a patient's care trajectory. This measure has an important place in cost measurement given that the episode-based measures will only apply to a subset of clinicians at this time. We recognize the MAP's reservations about this measure; however, as discussed in the CY 2020 PFS proposed rule (84 FR 40758), we believe that we have adequately addressed the mitigating factors outlined by the MAP. The MAP requested greater transparency around the attribution model and testing results, including examining validity and the impact of social risk factors, which we have addressed through the measure justification form we posted made publicly available, as well as our discussions with stakeholders at the MAP and through further education and outreach activities. The measure justification form is available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). With regard to actionability, this measure has been refined to identify more effectively primary care relationships between clinicians and patients and attribute clinicians who are involved in the ongoing management of a patient's primary care. We believe the proposed revisions make it a more targeted measure focused on costs for primary care and it will provide actionable feedback about primary care clinicians' cost performance.

Comment: Some commenters expressed concerns that the revised total per capita cost measure includes costs that are outside the reasonable control of a provider because the measure captures costs associated with care provided by others and costs they cannot influence, such as drug prices. Some commenters expressed concern that clinicians who manage care would be disadvantaged by this measure.

Response: The revised total per capita cost measure continues to use payment standardized prices to account for differences in Medicare payments for the same service across Medicare suppliers for all services included in the measure, including for Part B drugs. The measure does not include Medicare Part D costs, as these costs are not yet payment-standardized. We are currently considering the feasibility of developing

a payment standardization for Part D costs to account for factors that are outside the control of clinicians. The measure development contractor would seek input from expert panels when considering the inclusion of Part D costs in cost measures, and any additions of Part D costs to measures implemented in MIPS would be addressed through future rulemaking. The total per capita cost measure focuses on primary care by design and includes all costs to provide a broad assessment of a clinician's management of the overall health of a patient, rather than a specific condition. In managing a patient's complete health, clinicians measured under the total per capita cost measure are incentivized to conduct patient follow-up, coordinate care amongst specialists, offer necessary referrals, and actively diagnose patients. Clinicians managing patients' care are the focus of this measure and are compared to their peers performing similar roles.

Comment: Some commenters opposed the revised total per capita cost measure attribution methodology, specifically the process for establishing a primary care relationship between a patient and a clinician and how to define the end of a clinician responsibility for a patient. Some commenters indicated that this could be confusing for clinicians to understand. One commenter suggested that the revised attribution methodology could lead to multiple episodes occurring concurrently for the same clinician and patient. A few commenters expressed concern that the new attribution methodology did not have a method of establishing the end of a primary care relationship and could hold clinicians accountable for care after they were no longer managing care. Some commenters suggested that more than two services should be required to establish a primary care relationship. One commenter expressed concern that the attribution methodology did not account for patients who may reside in multiple localities throughout the year. One commenter expressed concern that that new attribution methodology does not properly reflect primary care relationships and identified cases in which a relationship would be identified through the methodology that were inappropriate, such as a clinician performing a pre-operative clearance. This commenter also identified situations in which a primary care relationship would not be established, such as when a clinician only sees a healthy patient once during the period. One commenter expressed concern that excluding specialists would reduce alignment between specialists and primary care clinicians.

Response: The triggering methodology for the revised total per capita cost measure aims to effectively identifying a primary care relationship between a clinician and a patient by requiring two claims, a ''primary care'' E/M code (that is, an outpatient E/M code identified as being for primary care) and an additional ''primary care'' E/M code or primary care service. Requiring two claims within a defined, relatively short period and using multiple codes indicative of overall health care E/M ensures that clinicians are attributed based on evidence of a sustained relationship rather than a single patient visit. Requiring more than two claims would restrict the clinicians that can be measured and limit the beneficiary cohort to only those with more frequent physician services, who are usually sicker. On the other hand, we do not believe that a single E/M code is sufficient evidence to indicate that a clinician and patient have begun an ongoing relationship. We considered it prudent not to attribute patients to clinicians they have seen only for a single visit to avoid the risk of misattribution. In addition, the exclusion rules that we proposed to add ensure that the measure effectively captures clinicians who provide primary care. We exclude certain specialties that are unlikely to provide primary care from triggering events within a clinician group. We also examine clinician billing patterns to characterize a clinician's role as this may indicate that they are unlikely to be providing primary care; for example, we exclude clinicians who exceed a low threshold of beneficiaries in which they are providing anesthesia, global surgery, therapeutic radiation, and/or chemotherapy. These rules ensure that we properly attribute clinicians with established primary care relationships.

The revised total per capita cost measures the overall cost of care delivered to a beneficiary with a focus on the primary care they receive. Primary care, by its nature, is ongoing and may span a long period so the revised total per capita cost measures clinicians for one year following an attribution event where evidence of a primary care relationship is identified. A longer attribution window allows the cost measure to capture the long-term benefits of ongoing primary care management that might not be fully realized within a short period. For example, preventive care services contribute cost to the measure when initially provided but should lower cost when measured over a sufficiently long time as they might avoid downstream costs that usually result from lack of preventive care. The clinician may continue to be attributed in a subsequent performance period if they bill new services that constitute a candidate event during an already open period of responsibility. In this construction, if multiple windows of attribution are opened, the attributed beneficiary months across the windows are consolidated into a continuous timeline of care. The clinician's responsibility for the attributed patients ultimately ends one year after the last attributable clinical event occurs. For patients with multiple residences during the year, the proposed revision to attribution would allow clinicians in both locations to be attributed concurrently, which would encourage coordination of care.

Comment: Some commenters supported the change in attribution methodology that would exclude certain clinicians based on their provision of certain services, but expressed concern that physician assistants (PAs) and nurse practitioners (NPs) that work in collaboration with excluded specialties would still be attributed patient costs based on this methodology. Some commenters recommended an expansion of excluded specialties to include hematology, medical oncology, radiation oncology, hospitalists, specialties providing perioperative care and rheumatology. Some commenters recommended that group composition be considered in determining attribution at the TIN level, such as by assessing the number of individual clinicians who might be eligible or by excluding attribution to physician assistants or nurse practitioners in groups that primarily contained other clinicians who did not provide primary care.

Response: We appreciate the support for the revised attribution methodology. We have assessed the frequency of TINs being attributed solely though physician assistants and nurse practitioners, and found that this occurs infrequently. We believe that it is appropriate to attribute clinicians and clinician groups that appear to provide primary care services in the claims data and expect that multi-specialty TINs may include a wide range of specialties. Detailed information on testing results for specialties attributed within TINs can be found in the MACRA Cost Measures Post-Field Testing materials that are publicly available from the Quality Payment Program Webinar Library at *https://qpp.cms.gov/about/webinars.* Hospitalists, medical oncologists, and radiation specialties, as defined by the CMS provider specialty code, are

excluded from the revised total per capita cost measure, as they are not expected to provide primary care services. Other oncology specialties, including hematology oncology, medical oncology, gynecological oncology, and rheumatology are not excluded from the measure as they are likely to provide primary care services in the form of managing a chronic disease.

Comment: Some commenters suggested that the revised total per capita cost measure should also include service-level exclusions.

Response: The measure continues to capture all costs within a defined timeframe. Broad, population-based measures provide an important means of measuring healthcare spending as they capture a wide range of patients and, consequently, allow for more comparability between clinicians who are covered by the same measure. As a broad population-based, measure focused on primary care and clinicians that provide primary care services, the revised total per capita cost measure can produce meaningful results to pinpoint areas at the provider-level for improvements in cost efficiency while ensuring high-quality primary care.

By including all services, the measure is able to fully capture the broad range of services during a defined period and incentivize primary care clinicians to correctly diagnose and appropriately manage diseases, including specialty referrals.

Comment: Many commenters expressed concern that they would be held accountable for the total per capita cost measure without having access to data to improve performance. Some commenters recommended that implementation of the measure be delayed at least a year to allow clinicians to review feedback. A few commenters asked that feedback on the measure be provided earlier and more frequently. One commenter indicated the difficulty for QCDRs in helping clinicians in working in this category without access to cost data on attributed patients. One commenter requested that CMS provide a report with the risk adjustment for all of their attributed patients under this measure.

Response: We will consider these suggestions for future rulemaking. In July 2019, we did provide reports with detailed data on the total per capita cost measure as specified for the 2018 MIPS performance period. We will continue to provide this level of detailed data. We will also continue to consider ways to offer actionable data and feedback on cost measures to clinicians in the future, including the frequency and format of the performance data provided.

Comment: Some commenters expressed concern that under the revised total per capita cost measure, beneficiary costs are counted multiple times as they may be attributed to multiple clinicians or clinician groups, even if they are not practicing as a team.

Response: While beneficiary costs can be attributed to multiple clinicians or clinician groups, the measure calculation compares each clinician's observed episode costs to the predicted episode costs among their peers for patients with the same observable characteristics, rather than to a pre-defined standard. By comparing clinicians to their peers, who are all attributed in the same way, we can expect this comparison to be fair. This approach reflects the team-based nature of primary care, which has been emphasized in stakeholder feedback, and allows attribution to reflect changes in a beneficiary's primary care provider such as beneficiaries who move during the year. We believe that it is important to measure all clinicians who are responsible for playing a role in a patient's care, particularly as the scoring of the cost category is comparative to peers. Jointly responsible clinicians should each be recognized while collaborating to provide patient care.

Comment: A few commenters expressed concern that clinicians in rural areas would be shown to have poor performance on the measure because of the nature of the area in which they practice. They suggested that smaller referral networks would reduce the opportunity for clinicians to help manage costs. A few commenters recommended that CMS winsorize, or limit extreme values in the measure score distribution, at the 95th percentile rather than the 99th percentile to address this issue. A few commenters recommended that rural clinicians only be compared to one another rather than to clinicians in urban or suburban settings.

Response: The measure development contractor performed detailed testing on the revised total per capita cost measure to ensure that all clinicians are measured accurately and fairly, regardless of size, location, or the population they serve. This testing includes stratifying clinician measure scores by defining characteristics and investigating the clinician score distribution by percentile. Stratification is performed for each of the following characteristics: Urban/rural, census division, census region, risk score, and the number of beneficiary months attributed to the clinician. We analyze the distribution of measure scores for clinicians defined by these characteristics, as well as for the overall measure to ensure that there is a sufficiently large difference in measure scores among clinicians to determine a meaningful difference in performance. More information on testing for this measure, including how we determine meaningful differences in clinician performance, is available in the measure justification forms available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*).

Winsorizing, or limiting extreme values in the measure score distribution at the 95th percentile, as suggested, would narrow the distribution that determines the most costly clinicians, which would diminish clinicians' ability to distinguish themselves compared to their peers. This portion of the distribution represents an area where the least cost efficient care is realized so it is advantageous to consider it when calculating measure scores. The National Summary Data Report available on the MACRA feedback page shows similar score distributions for urban and rural clinicians, which indicates that they perform similarly under the revised total per capita cost measure. Given the similar performance distribution between rural and urban clinicians, limiting the measure at the 95th percentile would be unlikely to advantage rural clinicians relative to urban clinicians.

Comment: A few commenters expressed concern about the risk adjustment used in the updated total per capita cost measure. A few commenters opposed the method of determining risk in 4-week blocks, believing that it added unnecessary complexity. One commenter expressed concern that HCC risk adjustment does not capture the risks associated with newly onset diseases such as cancer because the adjustment is based on a period prior to the measurement period.

Response: The risk adjustment model for the revised total per capita cost measure accounts for beneficiary-level risk factors that can affect medical costs, regardless of the care provided. The performance period is a 1-year long period that is divided into 13, 4-week blocks called beneficiary-months. Beneficiary-months that occur during a risk window and the measurement period are counted towards a clinician's or clinician group's measure scores. To ensure that the risk adjustment model

measures the influence of health status, as measured by diagnoses, on the treatment provided (costs incurred) rather than capturing the influence of treatment on a beneficiary's health status, the risk adjustment model uses risk factors from the year prior to each beneficiary-month. Dividing the performance period during which costs are assessed into 13 beneficiary-months allows the measure and the risk adjustment model to reflect changes in patient health characteristics that emerge throughout the performance period, including newly onset diseases. This refinement avoids measuring annualized costs for beneficiaries whose death date occurs during the performance period, which otherwise could potentially disincentivize care for more vulnerable patients.

Comment: A few commenters expressed concern that the total per capita cost measure did not properly include risk adjustment for socioeconomic issues, which the commenters suggested were a common reason for higher costs.

Response: Currently, risk adjustors for dual-eligibility and sex are included in the revised total per capita cost measure. As part of the standard development and re-evaluation processes, the measure development contractor conducted analyses to assess the impact of the following social risk factors: Income, education, employment, race, sex, and dual-eligibility status. Discussion of these results can be found in the measure justification form for the revised total per capita cost measure on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). Our analyses indicate that the inclusion of social risk factors in the current risk adjustment model has a minor effect on measure scores. We will continue to monitor the effect of social risk factors on the revised measure on an ongoing basis.

Comment: One commenter expressed concern that clinicians would not be able to track their performance from year to year due to the revisions in the specifications for the total per capita cost measure. This commenter recommended that the performance on the measure from previous years be recalculated.

Response: As the revised total per capita measure continues to measure the overall cost of care delivered to a beneficiary with a focus on the primary care they receive from a clinician, we believe clinicians will be able to compare their performance from year to year and across iterations of the measure. Clinician performance amongst peers will continue to be measured under the same methodological conditions and assumptions so a clinician's relative performance would be comparable across iterations of the measure. At this time, we do not plan to recalculate performance on the revised measure for years prior to 2020.

Comment: One commenter expressed concern that measuring costs on a monthly basis in the revised total per capita cost measure could result in clinicians with as few as 2 patients meeting the case minimum of 20.

Response: To clarify, the revised total per capita cost measure has a case minimum of 20 beneficiaries. If an ongoing primary care relationship is established between a clinician and patient, the clinician will be attributed beneficiary-months for the patient and for a year. Clinicians will only be scored on the measure if they are attributed beneficiary-months across at least 20 patients.

After consideration of the public comments, we are finalizing our proposal to include the total per capita cost measure with the revised specifications as proposed in the cost performance category beginning with the CY 2020 performance period.

(B) Medicare Spending Per Beneficiary Clinician Measure

Similar to the total per capita cost measure, we finalized the MSPB clinician measure for use in MIPS as an important measurement of clinician cost performance. Having been used in the Physician VM program, it had been tested and was reliable for Medicare populations and was familiar to the clinician community. However, when we finalized this measure for use in MIPS, we noted that as with all the cost measures, we will maintain this measure and update its specifications as appropriate (82 FR 53643). We continue to believe that the existing measure is appropriate to use in MIPS and continue to be committed to maintaining this cost measure with consideration of stakeholder input and testing. Hence, we re-evaluated the MSPB clinician measure as part of our routine measure maintenance. The re-evaluation was informed by feedback received on this measure through prior public comment periods, as described in the CY 2017 Quality Payment Program final rule (81 FR 77017 through 77018) and the CY 2018 Quality Payment Program final rule (82 FR 53577 through 53578), as well as feedback that arose in the measure development contractor's discussions with the standing TEP during the process of re-evaluation. This feedback is summarized below:

- The attribution methodology did not recognize the team-based nature of inpatient care;
- The attribution based on the plurality of Part B service costs during index admission could potentially attribute episodes to specialties providing expensive services as opposed to those providing the overall care management for the patient; and
- The measure captured costs for services that are unlikely to be influenced by the clinician's care decisions.

The feedback summarized above informed the two modifications that we proposed as part of the re-evaluation of this measure.

First, we proposed to change the attribution methodology to distinguish between medical episodes (where the index admission has a medical MS–DRG) and surgical episodes (where the index admission has a surgical MS–DRG) (84 FR 40759). A medical episode is first attributed to the TIN billing at least 30 percent of the inpatient E/M services on Part B physician/supplier claims during the inpatient stay. The episode is then attributed to any clinician in the TIN who billed at least one inpatient E/M service that was used to determine the episode's attribution to the TIN. A surgical episode is attributed to the surgeon(s) who performed any related surgical procedure during the inpatient stay, as determined by clinical input, as well as to the TIN under which the surgeon(s) billed for the procedure. The list of related surgical procedures MS–DRGs may be found in the measure codes list for the revised measure on the MACRA Feedback page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). This revised attribution methodology accounts for the team-based nature of care provided when managing medical conditions during an inpatient stay and allows for attribution to multiple clinicians to ensure that all clinicians involved in a beneficiary's care are appropriately attributed.

Second, to account for the more limited influence clinicians' performance has on costs when compared with hospitals, we proposed to add service exclusions to the measure to remove costs that are unlikely to be influenced by the clinician's care decisions (84 FR 40759). Specifically, we proposed to exclude unrelated services specific to groups of MS–DRGs aggregated by major diagnostic

categories (MDCs). Some examples of unrelated services include orthopedic procedures for episodes triggered by MS–DRGs under Disorders of Gastrointestinal System (MDC 06 and MDC 07) or valvular procedures for episodes triggered by MS–DRGs under Disorders of the Pulmonary System (MDC 04).

Further detail about these changes to the measure is included in the measure specifications documents, which are available at the MACRA Feedback page. This includes a comparison of the changes against the MSPB clinician measure as currently specified. A measure justification form containing testing results for this measure with the revisions is available on the MACRA Feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html.* We proposed to include the revised MSPB clinician measure with these specifications in the cost performance category beginning with the CY 2020 performance period (84 FR 40758).

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed attribution changes in the MSPB measure, in particular the separate attribution methods developed for medical and surgical episodes.

Response: We thank the commenters for their support for the revised measure.

Comment: Several commenters expressed general opposition to the inclusion of the revised MSPB measure in the MIPS program, noting that the measure was conditionally supported by the MAP pending review by the NQF but that there had been general concerns about the measure's risk adjustment and attribution. Some commenters suggested that only episode-based measures be included in the cost performance category, because they better identified the services that clinicians could influence.

Response: After its review of the proposed revisions to MSPB clinician measure, the MAP finalized a recommendation of ''conditional support for rulemaking'' with the condition that the revised measure be submitted for NQF endorsement. We plan to submit the revised measure to a future endorsement cycle; however, NQF endorsement is not required for cost measures to be implemented in the program. Following the MAP, the measure development contractor conducted testing of scientific acceptability, including statistical calibration of the risk adjustment model and reliability testing to assess the measure's attribution methodology. The testing results were made available in the measure justification form available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). We believe we have addressed the concerns raised by the MAP and that these revisions will ensure that the MSPB clinician measure continues to play an important role in the MIPS cost performance category.

We also continue to believe that the revised MSPB clinician measure provides an important measurement of clinician cost performance (82 FR 53644) complementing the episode-based measures. This measure evaluates the broad care related to an inpatient stay, which is a distinct measure focus from episode-based measures, which are intended to be more granular. By including both population- and episode-based measures in the cost performance category, a broader range of clinician care can be captured.

Comment: Some commenters expressed concerns that the revised MSPB clinician measure includes costs that are outside of the control of a provider because the measure captures costs associated with care provided by others and costs they cannot influence, such as drug prices. One commenter expressed concern that the measure only considered Medicare fee-for-service (FFS) patients, particularly since the health status of patients on Medicare Advantage may differ from those using Medicare FFS.

Response: As a population-based measure, the MSPB clinician measure is intended to reflect the cost to Medicare for a beneficiary's inpatient hospitalization. The measure does not include Medicare Part D costs and Part B drug costs that are included are payment standardized to remove factors outside the influence of clinicians. In addition, the revised measure excludes a list of services determined to be out of the influence of the clinician. The measure development contractor obtained input from the standing TEP and the MSPB Service Assignment Workgroup to identify and remove costs unlikely to be influenced by clinicians managing an acute inpatient stay. The MSPB Service Refinement Workgroup considered empirical analyses to identify service exclusions specific to Major Diagnostic Category (MDC) groupings, determined by the MS–DRG of the index admission. Based on these analyses, the MSPB Service Refinement Workgroup recommended exclusions for services that were unlikely to be under the influence of the clinician, and these exclusions were applied to revised MSPB clinician measure. Regarding the exclusive focus on FFS patients, the MSPB clinician measure is intended to focus on patients enrolled only in Medicare Parts A and B. While the covariates included in the risk adjustment model for the MSPB clinician measure are derived from the Medicare Advantage risk adjustment model, the risk scores (that is, normalized coefficients for each covariate) are not. MSPB clinician predicts regressions using MSPB episodes for FFS patients so that the expected spending related to certain conditions corresponds to the patient population being measured.

Comment: A few commenters expressed concern about the attribution methodology for the revised MSPB measure. A few commenters expressed concern about using different attribution methods for medical and surgical episodes. One commenter opposed using different attribution methods because surgical care is often provided for a medical condition. One commenter expressed concern that certain specialties of clinician, such as pathology, could be attributed the costs of care inappropriately.

Response: The changes to the attribution method of the revised MSPB clinician measure involves the use of separate attribution methods for medical and surgical episodes to identify the clinician(s) responsible for providing these different types of care and properly capture costs for more or less expensive episodes. The new methodology shifts attribution of episodes towards specialties that are more likely to be involved in managing the course of a patient's care, as we have heard concerns from stakeholders regarding the old methodology potentially attributing clinicians who do not provide the overall care management for a beneficiary. Additionally, the risk adjustment for the revised measure is ran within each MDC, and not between medical and surgical episodes. This allows for more accurate comparisons of predicted episode spending between clinicians treating patients with similar characteristics, rather than all attributed clinicians. Lastly, it is possible for specialties such as pathology to be attributed the revised MSPB clinician measure, as long as the pathologist is involved in the inpatient care of a patient and meets the attribution requirements.

Comment: A few commenters expressed concern with how the MSPB clinician measure performance would be determined by the specialty of the clinician. They indicated that a specialty adjustment had been used on the measure as part of the VM program and expressed concern that the new measure would not include that adjustment. A few commenters expressed concern that specialties practicing in teams may not be attributed properly under the new measure.

Response: To clarify, the MSPB measure currently in use in MIPS and the revised MSPB clinician measure do not include a specialty adjustment. However, the revised MSPB clinician has been refined to ensure effective attribution and compare similar clinicians. This is achieved by distinguishing between medical episodes and surgical episodes and risk adjusting for episodes within each MDC. These refinements allow for more accurate comparisons of predicted episode spending as clinicians are compared to other clinicians treating patients with similar characteristics, rather than being compared to all clinicians.

Comment: One commenter expressed concern that under the revised MSPB clinician measure, costs for patients could be counted for more than one clinician or group and results of the measure could be misleading. One commenter suggested that only certain costs should be included in the MSPB measure, not all costs that occur during the episode.

Response: The revised MSPB clinician measure assesses the cost to Medicare as a result of the services performed by an individual clinician during an MSPB clinician episode, which comprises the period immediately prior to, during, and following a patient's inpatient hospital stay. The measure was refined to exclude a defined list of services that are unlikely to be influenced by the clinician's care decisions and that are considered clinically unrelated to the management of care. The service exclusion rules are defined specific to the MDC of the index admission and were developed with expert clinical input from the MSPB Service Refinement Workgroup. Clinicians can choose how to participate in MIPS and have the option to report as a group or as individuals. Under the revised MSPB clinician measure, an episode can be attributed to multiple clinicians or clinician groups. The measure calculation risk adjusts each clinician's or clinician group's observed costs for patients with the same observable characteristics among their peers, rather than to a pre-defined standard. Given that the inpatient hospital setting is an important contributor to overall Medicare spending, gauging the efficacy of this spending requires measuring the cost performance of clinicians providing care at hospitals. The MSPB clinician measure provides valuable context for such progress in efficiency by measuring costs of care from a holistic perspective at the beneficiary level. Detailed information on how the MSPB clinician measure is calculated is provided in the measure methodology document available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*).

Comment: A few commenters expressed concern about not receiving detailed feedback on the revised MSPB measure before it was proposed for use in the cost performance category. A few commenters recommended that the measure implementation be delayed by one year to allow more time for clinicians to review data.

Response: In Fall 2018, we conducted extensive field testing for this measure. In addition to field test reports that provided detailed performance feedback to clinicians and clinician groups who met the 35 episode case minimum, we provided public documentation such as measure methodology documents with detailed descriptions of the revisions to the measure, a fact sheet, and an FAQ. We also held public webinars to provide more information about the revised measure methodology. Subsequently, the measure underwent MAP review, which provided stakeholders more opportunities to provide feedback about the measure prior to its proposal for implementation. As such, we believe that the measure is ready for implementation at this time, and that it is not necessary to delay its implementation to a future year.

Comment: A few commenters expressed concern that clinicians in rural areas would be shown to have poor performance on the measure because of the nature of the area in which they practice. They suggested that smaller referral networks would reduce the opportunity for clinicians to help manage costs. A few commenters recommended that CMS Winsorize, or limit extreme values in the MSPB clinician measure score distribution, at the 95th percentile rather than the 99th percentile to address this issue.

Response: The measure development contractor performed detailed testing on the revised MSPB clinician measure to ensure that all providers are measured accurately and fairly, regardless of size, location, or the population they serve. This testing includes stratifying clinician measure scores by defining characteristics and investigating the clinician score distribution by percentile. Stratification is performed for each of the following characteristics: Urban/rural, census division, census region, risk score, and the number of episodes attributed to the clinician. We analyze the distribution of measure scores for clinicians defined by these characteristics, as well as for the overall measure to ensure that there is a sufficiently large difference in measure scores among clinicians to determine a meaningful difference in performance. Our testing results show similar score distributions for urban and rural clinicians, which indicates that they perform similarly under the revised MSPB clinician measure. More information on testing for this measure, including how we determine meaningful differences in clinician performance, is available in the measure justification form available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). The revised MPSB clinician measure methodology aims to limit the effects of certain values in the measure score distribution in two ways. First, the expected episode cost is winsorized at the lower bound by assigning the value of expected episode costs at the 0.5th percentile of the distribution for episodes within the same MDC to all expected costs below the 0.5th percentile. Second, after winsorization, the measure excludes episodes with residual values below the 1st percentile and above the 99th percentile. Winsorizing expected episode cost at the 95th percentile would lower expected spending for the most complex patients and make it more difficult for clinicians to perform well. Lowering the threshold at which episodes with high residuals are excluded to the 95th percentile would narrow the distribution by removing more costly clinician episodes, which would diminish clinicians' ability to distinguish themselves compared to their peers. This portion of the distribution represents an area where the least cost-efficient care is realized so it is advantageous to consider it when calculating measure scores. After consideration of the public comments, we are finalizing our proposal to

include the MSPB clinician measure with the revised specifications as proposed in the cost performance category beginning with the CY 2020 performance period.

(vi) Reliability

(A) Reliability for Episode-Based Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77170), we finalized a reliability threshold of 0.4 for measures in the cost performance category. In the CY 2019 PFS final rule, we established at § 414.1350(c)(4) and (5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures and 10 episodes for procedural episode-based measures (83 FR 59773 through 59774). We examined the reliability of the 10 episode-based measures listed in Table 45 at our established case minimums and found that all of these measures meet the reliability threshold of 0.4 for the majority of groups at a case minimum of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures. All of the measures meet this standard at the individual clinician level as well, with the exception of the Lower Gastrointestinal Hemorrhage episode-based measure. In section III.K.3.c.(2)(b)(vi)(B) of the proposed rule, we discuss a proposal to limit our assessment of certain cost measures to groups (identified by a TIN) based on the results of our reliability analysis (84 FR 40760).

TABLE 45: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Acute Kidney Injury Requiring New Inpatient Dialysis	100.0%	0.58	85.3%	0.48
Elective Primary Hip Arthroplasty	100.0%	0.85	100.0%	0.78
Femoral or Inguinal Hernia Repair	100.0%	0.86	100.0%	0.81
Hemodialysis Access Creation	93.1%	0.63	70.1%	0.48
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	100.0%	0.69	68.0%	0.46
Lower Gastrointestinal Hemorrhage*	74.6%	0.51	0.0%	0.20
Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels	100.0%	0.77	100.0%	0.69
Lumpectomy Partial Mastectomy, Simple Mastectomy	100.0%	0.64	100.0%	0.60
Non-Emergent Coronary Artery Bypass Graft (CABG)	100.0%	0.82	100.0%	0.74
Renal or Ureteral Stone Surgical Treatment	100.0%	0.77	100.0%	0.65

*This measure was proposed only for groups. Please reference section III.K.3.c.(2)(b)(vi)(B) of the final rule.

(B) Limiting Assessment of Certain Measures to Groups

We have assessed clinicians and groups on cost measures when they meet the case minimum for a measure. As part of our efforts to ensure reliable measurement, we have examined the reliability of cost measures at the group and individual level, as clinicians are able to participate in MIPS in either way. However, for clinicians who participate in MIPS as individuals, we have found the Lower Gastrointestinal Hemorrhage episode-based measure does not meet the reliability threshold of 0.4 that we established for measures in the cost performance category. While we considered not including the measure in MIPS for this reason, we do find that this measure meets the reliability threshold for those who participate in MIPS as part of a group. Therefore, we proposed to include the measure in the cost performance category only for MIPS eligible clinicians who report as a group or virtual group (84 FR 40760). We will continue to assess the reliability of cost measures for group and individual participation as the measures are introduced or are revised. If we identify measures that are similarly found to meet our reliability threshold at the group level but not at the individual level, we will again consider limiting the assessment of the measure to groups.

The following is a summary of the comments we received and our responses.

Comment: A few commenters generally agreed that the mean reliability for the Lower Gastrointestinal Hemorrhage episode-based measure at the TIN/NPI level is too low and should be used at the group level. One commenter indicated that the reliability is too low at the individual level and requested more details on the range of reliability values by practice size. The commenter also requested that CMS consider an exclusion for small practices for whom reliability is lower than the TIN mean of 0.51.

Response: While we have not examined the relationship between practice size and the reliability of the cost measures, we have examined the relationship between case volume and the reliability of cost measures. The measure justification form for this measure, which is available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*), presents reliability at three different case sizes or volume thresholds. To some degree, the size of a practice may correlate with the case size for cost measures, as an individual clinician can only see so many patients.

We believe that establishing case minimums that are based on moderate reliability allows us to measure all clinicians and groups that meet those case minimums. As such, we do not believe that small practices who meet the moderate reliability threshold of 0.4 but are below 0.51 should be excluded. We have established a small practice bonus within the quality performance category to accommodate the issues small practices may face. We will take the recommendation to provide additional reliability figures into consideration when providing future measure testing results and continue to monitor cost performance and reliability for small practices to ensure that the measures continue to accurately and fairly measure their performance.

Comment: A few commenters expressed concerns that the 0.4 threshold is too low to ensure reliability and clinicians should not be held accountable for measures at this level of reliability. A few commenters recommended that CMS adopt a higher reliability such as 0.75 or 0.7. Additionally, a few commenters stated that the established case minimums should be set higher even though this may lead to fewer clinicians being attributed to the measure.

Response: We appreciate the input on reliability thresholds. We finalized a reliability threshold of 0.4 for measures in the cost performance category in the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77170) that is consistent with other CMS quality programs. We generally consider reliability levels between 0.4 and 0.7 to indicate ''moderate'' reliability and levels above 0.7 to indicate ''high'' reliability. In cases where we have considered high participation in the applicable program to be an important programmatic objective, we have selected the 0.4 moderate reliability standard. We believe this standard ensures moderate reliability but does not substantially limit participation.

All measures proposed, with the exception of the Lower Gastrointestinal Hemorrhage measure that was proposed at the group level only, exceed the threshold at the clinician and clinician group level (84 FR 40759 through 40760). Detailed information about the development and reliability testing of the episode-based measures and revised cost measures is publicly available for download on the MACRA Feedback Page (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html*).

After consideration of the comments, we are finalizing our proposal to include the Lower Gastrointestinal Hemorrhage episode-based measure in the cost performance category only for MIPS eligible clinicians who report as a group or a virtual group.

(C) Reliability for Revised Cost Measures

In the CY 2017 Quality Payment Program final rule, we finalized a reliability threshold of 0.4 for measures in the cost performance category (81 FR 77169 through 77170). Additionally, we established a case minimum of 35 episodes for the MSPB clinician measure (81 FR 77171) and a case minimum of 20 beneficiaries for the total per capita cost measure (81 FR 77170). We codified these case minimums at § 414.1350(c)(1) and (2) in the CY 2019 PFS final rule (83 FR 59774). We based these case minimums on our interest in ensuring that the majority of clinicians and groups that were measured met the threshold of 0.4 reliability, which we believed best balanced our interest in ensuring moderate reliability without limiting participation. Given the significant changes to these measures that we proposed in section III.K.3.c.(2)(b)(v) of the proposed rule (84 FR 40757 through 40759), we again examined the reliability of the revised MSPB clinician and total per capita cost measures at these case minimums and found that the measures meet the reliability threshold of 0.4 for the majority of clinicians and groups at the existing case minimums, as shown in Table 46.

TABLE 46—PERCENT OF TINS AND TIN/NPIS THAT MEET 0.4 RELIABILITY THRESHOLD FOR THE REVISED MSPB CLINICIAN AND TOTAL PER CAPITA COST MEASURES

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability TINs	% TIN/NPIs meeting reliability threshold	Mean reliability TIN/NPIs
Medicare Spending per Beneficiary Clinician	100	0.77	100	0.69
Total Per Capita Cost	100	0.82	100	0.89

Based on this analysis, we did not propose any changes to the case minimums, which we previously finalized as 35 for the MSPB clinician measure, and 20 for the total per capita cost measure.

Comment: A few commenters favored a case minimum of 35 for the revised total per capita cost and MSPB clinician measures to improve reliability and promote consistency within the cost performance category.

Response: We do not believe it is necessary to increase the case minimum for the total per capita cost measure, as the majority of clinicians and clinician groups exceed the reliability threshold of 0.4 at the existing case minimum of 20 beneficiaries. Keeping this case minimum would balance the goal of increased reliability with the goal of adopting cost measures that are applicable to a larger set of clinicians and clinician groups.

(vii) Request for Comments on Future Potential Episode-Based Measure for Mental Health

We plan to continue to develop episode-based measures and propose to adopt them for the cost performance category in future rulemaking. As a part of these efforts, we seek to expand the range of procedures and conditions covered to ensure that more MIPS eligible clinicians have their cost performance assessed under clinically relevant episode-based measures. In recognition of the importance of assessing mental health care, we developed an acute inpatient medical condition episode-based measure for the treatment of inpatient psychoses and related conditions through the same process involving extensive expert clinician input as the measures in section III.K.3.c.(2)(b)(vii) of the proposed rule (84 FR 40760). The specifications for the Psychoses/Related Conditions episode-based measure are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-specs.zip.* The Psychoses/Related Conditions episode-based measure represents an

opportunity to incentivize improvement in the field of mental health, a CMS priority area. We refer readers to the CY 2020 PFS proposed rule where we summarize the MAP's feedback and recommendations regarding the Psychoses/Related Conditions episode-based measure (84 FR 40760).

In the CY 2020 PFS proposed rule, we solicited comments on the potential use of this new Psychoses/Related Conditions episode-based measure in the cost performance category in a future MIPS performance period (84 FR 40760). While we are not summarizing and responding to comments we received in this final rule, we thank the commenters for their responses, and we will consider them as we consider the potential inclusion of the Psychoses/Related Conditions episode-based measure in the future.

(viii) Summary of Previously Established and Finalized Measures for the Cost Performance Category for the 2020 and Future Performance Periods

The previously established and finalized measures for the cost performance category for the 2020 and future performance periods are summarized in Table 47.

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TABLE 47: Summary Table of Cost Measures for the 2020 Performance Period and Future Performance Periods

Measure Topic	Measure Type	Measure Status
Total Per Capita Cost	Population-Based	Revised and finalized for 2020 performance period and beyond
Medicare Spending Per Beneficiary Clinician	Population-Based	Revised and finalized for 2020 performance period and beyond
Elective Outpatient Percutaneous Coronary Intervention (PCI)	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond
Knee Arthroplasty	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond
Screening/Surveillance Colonoscopy	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition episode-based	Currently in use for 2019 Performance Period and Beyond
Simple Pneumonia with Hospitalization	Acute inpatient medical condition episode-based	Currently in use for 2019 Performance Period and Beyond
ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition episode-based	Currently in use for 2019 Performance Period and Beyond
Acute Kidney Injury Requiring New Inpatient Dialysis	Procedural episode-based	Finalized for 2020 Performance Period and Beyond
Elective Primary Hip Arthroplasty	Procedural episode-based	Finalized for 2020 Performance Period and Beyond
Femoral or Inguinal Hernia Repair	Procedural episode-based	Finalized for 2020 Performance Period and Beyond
Hemodialysis Access Creation	Procedural episode-based	Finalized for 2020 Performance Period and Beyond
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	Acute inpatient medical condition episode-based	Finalized for 2020 Performance Period and Beyond
Lower Gastrointestinal Hemorrhage *(at group level only)*	Acute inpatient medical condition episode-based	Finalized for 2020 Performance Period and Beyond
Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels	Procedural episode-based	Finalized for 2020 Performance Period and Beyond
Lumpectomy, Partial Mastectomy, Simple Mastectomy	Procedural episode-based	Finalized for 2020 Performance Period and Beyond
Non-Emergent Coronary Artery Bypass Graft (CABG)	Procedural episode-based	Finalized for 2020 Performance Period and Beyond
Renal or Ureteral Stone Surgical Treatment	Procedural episode-based	Finalized for 2020 Performance Period and Beyond

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(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), and the CY 2019 PFS final rule (83 FR 59776 through 59777).

In this final rule, we are: (1) Modifying the definition of rural area; (2) updating § 414.1380(b)(3)(ii)(A) and (C) removing the reference to the four listed accreditation organizations to be recognized as patient-centered medical homes and removing the reference to the specific accrediting organization for comparable specialty practices; (3) increasing the group reporting threshold to 50 percent; (4) establishing factors to consider for removal of improvement activities from the Inventory; (5) removing 15, modifying seven, and adding two new improvement activities for the 2020 performance period and future years; and (6) concluding and removing the CMS Study on Factors Associated with Reporting Quality Measures. These are discussed in more detail in this final rule.

(b) Small, Rural, or Health Professional Shortage Areas Practices

For our previously established policies regarding small, rural, or Health Professional Shortage Areas Practices, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77188), CY 2018 Quality Payment Program final rule (82 FR 53581), and § 414.1305. In the CY 2018 Quality Payment Program final rule (82 FR 53581 through 53582), we changed the definition of rural area at § 414.1305 to mean ZIP codes designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available.

It has come to our attention that the rural area definition at § 414.1305 includes the incorrect file name for the rural designation. While we used the correct file, we just referenced it incorrectly. Therefore, in the CY 2020 PFS proposed rule (84 FR 40762), we proposed to update the MIPS rural area definition by correcting the file name. In the CY 2017 Quality Payment Program final rule (81 FR 77188), we incorrectly referenced the file we used for rural designation as ''*the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available*'' instead of the correct file entitled ''*Federal Office of Rural Health Policy (FORHP) eligible ZIP codes*'' which may currently be found at *https://www.hrsa.gov/rural-health/about-us/definition/datafiles.html.* The HRSA Area Health Resources Files (AHRF) include data on Health Care Professions, Health Facilities, Population Characteristics, Economics, Health Professions Training, Hospital Utilization, Hospital Expenditures, and Environment at the county, state and national levels, from over 50 data sources [115] but does not contain specific data on rurality developed by HRSA's FORHP. To be clear, we have been using the more appropriate FORHP eligible ZIP code file in all previous 3 years of MIPS; we simply inadvertently listed the incorrect file name in the definition. Furthermore, the definition of rural in MIPS is based on the rural definition developed by HRSA's FORHP which may be found at *https://www.hrsa.gov/rural-health/about-us/definition/index.html.* The FORHP defines all non-Metro counties as rural and uses an additional method of determining rurality called the Rural-Urban Commuting Area (RUCA) codes to designate rural Census Tracts within Metropolitan Counties. The FORHP eligible ZIP codes are available in a file located at *https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/aboutus/definition/forhp-eligible-zips.xlsx.* Therefore, we proposed to modify the definition of rural area at § 414.1305 to mean a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

We invited public comment on our proposal as discussed in this final rule. We did not receive any comments on this proposal. Therefore, we are finalizing our proposal, as proposed, to modify the definition of rural area at § 414.1305 to mean a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

(c) Patient-Centered Medical Home and Comparable Specialty Practice Accreditation Organizations

In the CY 2017 Quality Payment Program final rule (81 FR 77179 through 77180), we finalized at § 414.1380(b)(3)(ii) an expanded definition of what is acceptable for recognition as a certified-patient-centered medical home or comparable specialty practice. Specifically, we finalized that one of the criteria, as stated at § 414.1380(b)(3)(ii)(A), is whether the practice has received accreditation from one of four accreditation organizations that are nationally recognized; paragraphs (b)(3)(ii)(A)(1) through (4) list the four organizations with nationally recognized patient-centered medical home accreditation programs: (1) The Accreditation Association for Ambulatory Health Care; (2) the National Committee for Quality Assurance (NCQA) Patient-Centered Medical Home; (3) The Joint Commission Designation; or (4) the Utilization Review Accreditation Commission (URAC) (81 FR 77180). In addition, we finalized another criteria at § 414.1380(b)(3)(ii)(C), which states that the practice is a comparable specialty practice that has received the NCQA Patient-Centered Specialty Recognition (81 FR 77180). Further, we finalized that the criteria for being a nationally recognized accredited patient-centered medical home are that it must be national in scope and must have evidence of being used by a large number of medical organizations as the model for their patient-centered medical home (81 FR 77180).

Since finalizing these criteria, it has come to our attention that we may have inadvertently been excluding other organizations. It was and is not our intention to limit patient-centered medical home or comparable specialty practice accreditation organizations to those listed. We realize that there may be additional accreditation organizations that have nationally recognized programs for accrediting patient-centered medical homes and comparable specialty practices that were not included. Therefore, in the CY 2020 PFS proposed rule (84 FR 40763), we requested comments on our proposal to update § 414.1380(b)(3)(ii)(A) and (C) to remove specific entity names.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed removal of specific entity names from § 414.1380(b)(3)(ii)(A) and (C) because it broadened the criteria of a medical home and will be helpful to practices seeking to become accredited patient centered medical homes. One commenter stated that practices with these designations promote innovative delivery system reforms; meet stringent, robust criteria for clinical practice transformation; and are held to a high standard of care for the patients they serve.

[115] *https://data.hrsa.gov/topics/health-workforce/ahrf.*

Response: We appreciate the support. We clarify that we are not broadening or changing our criteria for accreditation organizations. We continue to believe that the criteria established, for what we considered certified at § 414.1380(b)(3)(iv) are appropriate and meet national guidelines. We are merely finalizing the removal of specific entity name examples at § 414.1380(b)(3)(ii)(A) and (C).

Comment: A few commenters did not support removing the names of the approved patient-centered medical home and comparable specialty practice programs that provide clinicians full credit for the MIPS improvement activities performance category. The commenters noted that the evidence-based formal patient-centered medical home criteria help to standardize effective practices and attributes in recognized practices, help payers standardize payments and compare performance without specifying which programs qualify. One commenter noted that without specifying which patient-centered medical home and comparable specialty practice programs qualify for certification, clinicians will lack assurance that participation in a given patient-centered medical home and comparable specialty practice program will earn the full improvement activities 15 points. The commenter recommended specifying and updating a public list of any additional qualified programs to address concern about excluding any programs that have the required national scope without creating uncertainty. One commenter noted that removing the named entities may encourage the development of patient-centered medical home programs with below par standards and recommended that we review any programs that are not reviewed by the four named accreditation organizations to ensure they meet the same high standards for rigor.

Response: We believe that removing specific patient-centered medical home accreditations organizations will level the playing field for any organization that meets the requirements. We refer readers to the Quality Payment Program website improvement activities landing page at *https://qpp.cms.gov/mips/improvement-activities,* where we have provided a few examples of accreditation organizations that are recognized or certified patient-centered medical home and comparable specialty practice programs. We disagree that removing the named entities may encourage the development of patient-centered medical home programs with below par standards as we are not broadening or changing our certification criteria for accreditation organizations. We are merely finalizing the removal of specific entity name examples at § 414.1380(b)(3)(ii)(A) and (C).

Comment: One commenter requested clarification whether the proposal to regulatory text impacts NCQA recognition for patient-centered medical home and comparable specialty practice programs and subsequently credit for the improvement activities performance category.

Response: We clarify that removing specific entity name examples of accreditation organizations from the regulations text does not speak to an organization's qualifications to provide accreditation for patient-centered medical homes and comparable specialty practices. It was and is not our intention to limit patient-centered medical home or comparable specialty practice accreditation organizations to those listed in the regulations text. We realize that there may be additional accreditation organizations that have nationally recognized programs for accrediting patient-centered medical homes and comparable specialty practices that were not included. This change is an effort to make the regulations text more neutral. We refer readers to the Quality Payment Program website at *https://qpp.cms.gov/mips/improvement-activities* where we have provided a few examples of accreditation organizations that are recognized or certified patient-centered medical home and comparable specialty practice programs.

After consideration of the comments, we are finalizing our proposal, as proposed, to update § 414.1380(b)(3)(ii)(A) and (C) to remove specific entity name examples.

(d) Improvement Activities Data Submission

We proposed changes to the improvement activities data submission for group reporting requirements, as discussed below.

(i) Submission Mechanisms

For our previously established policies regarding improvement activities performance category submission mechanisms, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53650 through 53656), the CY 2019 PFS final rule (83 FR 59777), and § 414.1360(a)(1). We did not propose any changes to these policies.

(ii) Submission Criteria

For our previously established policies regarding improvement activities performance category submission criteria, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77185), the CY 2018 Quality Payment Program final rule (82 FR 53651 through 53652), the CY 2019 PFS final rule (83 FR 59777 through 59778), and § 414.1380. We did not propose any changes to these policies.

(iii) Group Reporting

In the CY 2020 PFS proposed rule (84 FR 40763 through 40764), we made two proposals with respect to group reporting to: (a) Increase the group reporting threshold from at least one clinician to at least 50 percent of the group beginning with the 2020 performance year, and (b) at least 50 percent of a group's National Provider Identifiers (NPIs) must perform the same activity for the same continuous 90 days in the performance period beginning with the 2020 performance year. These are discussed in more detail below.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77181), in response to a public comment, we stated that if at least one clinician within the group is performing the activity for a continuous 90 days in the performance period, the group may report on that activity. In addition, we specified that all MIPS eligible clinicians reporting as a group would receive the same score for the improvement activities performance category if at least one clinician within the group is performing the activity for a continuous 90 days in the performance period (81 FR 77181).

In the CY 2018 Quality Payment Program proposed rule (82 FR 30053), we requested comment for future consideration on issues related to whether we should establish a minimum threshold (for example, 50 percent) of the clinicians (NPIs) that must complete an improvement activity for the entire group (Taxpayer Identification Number (TIN)) to receive credit in the improvement activities performance category in future years. Some commenters expressed concerns that setting a minimum threshold would add complexity or burden for clinicians. Other commenters supported the establishment of a minimum participation threshold in future years, noting that a minimum threshold will ensure scoring is reflective of care delivered by the group as a whole rather than one or a few high-performing clinicians.

We believe that by Year 4 (2020 performance year) of the Quality Payment Program, clinicians should be familiar with the improvement activities performance category. We believe that increasing the minimum threshold for a

group to receive credit for the improvement activities performance category will not present additional complexity and burden for a group. With over 100 improvement activities available for eligible clinicians to choose from in the improvement activities Inventory, which may be found at the Quality Payment Program website *https://qpp.cms.gov/,* that provide a range of options for clinicians seeking to improve clinical practice that are not specific to practice size, specialty, or practice setting. We believe that a group should be able to find applicable and meaningful improvement activities to complete that would apply to at least 50 percent of individual MIPS eligible clinicians in a group.

Therefore, in the CY 2020 PFS proposed rule (84 FR 40763), we proposed to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent for the improvement activities performance category beginning with the 2020 performance year and future years. We note that once finalized the changes to the group threshold will have no impact on the previously finalized policy that eligible clinicians participating in an APM will receive full points for the improvement activities performance category as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260). This is an increase to the previously established requirement finalized in the CY 2017 Quality Payment Program final rule (81 FR 77181) that only one clinician within a TIN needs to attest to the completion of an improvement activity to get credit towards the MIPS final score. We believe a 50 percent threshold is achievable and appropriate because, if a group or virtual group has implemented an improvement activity, the activity should be recognized and adopted throughout much of the practice to improve clinical practice, care delivery, and outcomes. This aligns with our definition of an improvement activity at § 414.1305. In crafting our proposal, we also considered other thresholds, such as a lower threshold of 25 percent. However, we believe that improvement activities should be adopted throughout much of the practice to achieve improved outcomes. We do not believe that 25 percent group participation will reflect improved outcomes. We also considered a higher threshold of 100 percent, but have concerns that requiring every clinician within a group to perform improvement activities may be premature at this time because increasing the threshold by such a large amount may be considered burdensome to clinicians. However, we believe that 50 percent provides an appropriate balance between requiring at least half of the NPIs reporting as part of a group to participate in the improvement activities performance category and acknowledging the challenges to requiring every NPI in a group to perform the improvement activity for a group to receive credit. We also believe our proposal aligns with the 50 percent threshold for the number of practice sites that must be recognized for a TIN to receive full credit as a patient-centered medical home (82 FR 53655) and is both achievable and appropriate at this time.

Furthermore, we believe that requiring at least 50 percent of a group or TIN to perform an improvement activity for the same continuous 90-day performance period will facilitate improvement in clinical practice within a TIN. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77186), we considered setting the threshold for the minimum time required for performing an activity to longer periods up to a full calendar year. However, after researching several organizations we stated that we believed a minimum of 90 days is a reasonable amount of time (81 FR 77186). In addition, in response to comments we stated that we believed that each activity can be performed for a full 90 consecutive days by some, if not all, MIPS eligible clinicians, and that there are a sufficient number of improvement activities included that any eligible clinician may select and perform for a continuous 90 days that will allow them to successfully report under this performance category (81 FR 77186).

Therefore, we requested comments on our proposal to revise § 414.1360(a)(2) to state that beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. To be clear, other submission requirements will remain the same. In other words, each TIN will need to submit an attestation for each improvement activity selected that at least 50 percent of its NPIs performed the same activity for the same continuous 90 days in the performance period. For example, TIN 1234 attests that at least 50 percent of its NPIs performed the improvement activity entitled: ''Participation in a QCDR that promotes use of patient engagement tools'' (IA_BE_7) for the same continuous 90-day period. Because IA_BE_7 is medium-weighted, the example TIN will receive 10 points toward the total possible improvement activities score. TIN 1234 also attests that at least 50 percent of its NPIs performed the improvement activity entitled: ''Implementation of formal quality improvement methods, practice changes, or other practice improvement processes'' (IA_PSPA_19) for the same continuous 90-day period. Because IA_PSPA_19 is medium-weighted, the example TIN will receive another 10 points toward the total possible improvement activities score. We refer readers to the CY 2019 Quality Payment Program final rule (83 FR 59753 through 59754) where we discuss the data submission deadline which was finalized at § 414.1325(e)(1) as follows: For the direct, login and upload, login and attest, and CMS Web Interface submission types, March 31 following the close of the applicable performance period or a later date as specified by CMS.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to have at least 50 percent of clinicians reporting as a group perform the same activity for the same continuous 90 days in the performance period as they noted that it would promote increased participation in the improvement activities performance category by clinicians in groups. They stated that it would ensure scoring is reflective of care delivered by the group as a whole rather than one or a few high-performing clinicians.

Response: We thank the commenters for their support.

Comment: Several commenters recommended alternative thresholds ranging from 5 to 25 percent, noting concerns that it may be impractical for groups to meet the proposed 50 percent threshold which could then disincentivize performance in the improvement activities performance category. A few commenters requested a more gradual increase to enable groups to amend current efforts to meet the policy requirement. Commenters recommended the development of a pilot program including options to test a gradual increase at a few sites and to test more feasible thresholds. A more reasonable number of eligible clinicians within groups who would be required to participate in an improvement activity because some improvement activities

lend themselves to widespread participation such as being part of a group that provides 24/7 access to care or participation in a Patient Safety Organization. One commenter recommended an alternative threshold that sets a percentage or minimum number of clinicians (such as 30) that does not limit options for large groups. One commenter recommended a percentage between 10 percent and 25 percent because 50 percent is too drastic of an increase and the ambiguity and uncertainty on how to quantify clinician participation at the 50 percent level. One commenter recommended a number between one clinician and 50 percent of clinicians is appropriate believing the correct number needs further study. One commenter stated this is a significant policy change and recommended a more gradual approach to a threshold of 25 percent. One commenter recommended a modification to 20 percent of total NPIs within a TIN believing it is a good sample size and would reduce burden. Another commenter recommended an alternative threshold of 1 percent or 5 clinicians, whichever is greater. One commenter recommended a cap on the number of providers required to attest, such as no more than 25 eligible clinicians from any one TIN. Another commenter recommended lowering the percentage or to provide for reporting to be 'by department' because there may be advantages for reporting at the department level. One commenter recommended delaying implementation of the 50 percent threshold until CY 2021 to give large groups adequate time to implement needed changes. One commenter requested clarification whether the proposal intends that the 50 percent threshold applies to 50 percent of the total NPIs under the TIN. Other commenters recommended an increase to 5 or 10 percent because raising the bar to 50 percent of clinicians in a group would significantly increase burden; making it impossible in some cases for groups to attest to the required number of improvement activities to receive partial or full credit for the performance category; and that there are few clinician leaders in a group who are actively engaged in a particular improvement activity. One commenter noted a 10 percent threshold is a reasonable compromise.

Response: We do not believe that setting thresholds at 5 percent, 10 percent, or 25 percent is appropriate as it does not provide a comprehensive representation of the entire group. We believe that requiring at least 50 percent of the group to perform the same activity provides an appropriate balance between requiring at least half of the NPIs reporting as part of a group to participate in the improvement activities performance category and acknowledging the challenges to requiring every NPI in a group to perform the improvement activity for a group to receive credit. The common goal of group reporting should be group practice transformation and improved patient outcomes. If each clinician is reporting on a different improvement activity, we do not believe that would meet the common goal of group reporting. Moreover, while we understand that one clinician completing an activity may have benefits, we do not believe that only one clinician completing an activity would create a widespread benefit for an entire group. While in some small groups, one participant may have a greater impact, for larger groups, one participant is a very low bar. We believe a 50 percent threshold is appropriate because it will encourage increased clinician participation, provide for more meaningful clinical practice transformation, and will require a level of clinician participation more appropriate for the group to receive credit. We believe increasing the threshold to at least 50 percent of the clinicians in the group moves the improvement activities performance category towards greater impact and value aligning with the MVP framework. In addition, using a 50 percent threshold for the group is less than what clinicians must do in other performance categories. In the quality performance category, we have established that 100 percent of the group, to the extent the group has patients that are applicable to the measure, must comply with our requirements (81 FR 77072). Additionally, for the cost performance category, we have established a 100 percent threshold to calculate those measures (81 FR 77072).

We believe a 50 percent threshold will increase clinician participation, provide for more meaningful clinical practice transformation, and require a level of clinician participation more appropriate for the MVP goal of greater value and impact. In addition, we believe a 50 percent threshold is achievable and appropriate because, if a group or virtual group has implemented an improvement activity, the activity should be recognized and adopted throughout much of the practice to improve clinical practice, care delivery, and outcomes. Furthermore, we believe that 50 percent provides an appropriate balance between requiring at least half of the NPIs reporting as part of a group to participate in the improvement activities performance category while acknowledging the challenges to requiring every NPI in a group to perform the improvement activity for a group to receive credit. This aligns with the 50 percent threshold for the number of practice sites that must be recognized for a TIN to receive full credit as a patient-centered medical home (82 FR 53655) and is both achievable and appropriate at this time. We do not believe that increasing the group threshold to 50 percent for improvement activities should hinder participation in other facility initiatives. We anticipate that in future rulemaking, we will continue to increase this threshold. Our future goal would be to have 100 percent of a group performing the same activity during any 90-day period within the same performance year.

We are unclear on why one commenter stated that there is ''ambiguity and uncertainty on how to quantify clinician participation at the 50 percent level''. If the commenter is requesting clarification on how to count clinicians towards the 50 percent when there is an uneven number of clinicians in the group. In that instance, the group would need to go up to the next whole number to account for 50 percent of the clinicians in the group. For example, if the group consists of 13 members then at least 7 clinicians would need to report the same improvement activity for any continuous 90 days in the performance year for the activity to count towards the improvement activity performance category score. The Inventory provides a detailed description of what is required to complete a particular activity. In addition, we have provided several resources such as a Quick Start Guide and Fact Sheet on the Quality Payment Program website at *https://qpp.cms.gov/about/resource-library.* If clinicians have further questions they may contact the Quality Payment Program service center at *QPP@cms.hhs.gov* or at 1–866–288–8292. We also believe that we are providing a gradual approach to increasing the group requirements for the improvement activities performance category, as for the first 3 years of MIPS we only required one clinician from a group to perform and report on an improvement activity. As we are preparing to enter Year 4 (CY 2020) of the program we believe we should increase the group reporting threshold for improvement activities to better align with the other performance categories.

We do not believe a pilot is necessary to attain information on whether a

group is capable of completing improvement activities from the Inventory as they are broad and are not specific to practice size, specialty, or practice setting. We understand that there are some improvement activities that might lend themselves to widespread participation. We also believe that groups are able to discern which activities would best meet the needs of their group.

Comment: Many commenters did not support the requirement for 50 percent of clinicians in the group to report on the same activity, rather than any activity, within the same 90-day window for group or virtual group improvement activity reporting, noting that it would be impractical. A few commenters recommended that we modify our proposal to a lower threshold which represents the percentage of clinicians in the group who satisfy any activity rather than the same activity over the same 90-day period. One commenter noted it would be impractical to expect all clinicians in a larger group to perform the same activity over the same 90-day period and recommended no change to the current policy. However, the commenter continued that if the policy is changed, then it should be modified to provide that a certain percentage of clinicians in the group (ideally less than 50 percent) can complete any single activity, rather than the same activity, over the performance year, rather than over the same 90-day period, if the same 90-day period would not apply to all those attesting to the activity. Another commenter recommended modifying the proposal to a certain percentage of clinicians in the group, for example, less than 50 percent, which must complete any single activity, rather than the same activity, over the performance year, rather than over the same 90-day period. One commenter recommended that clinicians within multi-specialty groups and virtual groups should elect the improvement activities that are most relevant to them and complete them in a 90-day window of the calendar year that best works with their patient, surgical, call and delivery schedule. One commenter expressed concerns about the ''erosion of flexibility'' in the improvement activities performance category. One commenter recommended modifying the proposal to require groups to complete at least 45 consecutive days during each of 2 consecutive performance periods believing this approach would lower burden on clinicians and encourage participation. A few commenters expressed concerns that a 50 percent threshold may be problematic for groups with a high percentage of clinician volunteers participating in Emergency Response and Preparedness activities such as ''Participation in a 60-day or greater effort to support domestic or international humanitarian needs'' (IA_ERP_2) that require staggered leaves to continue to provide care to their local patients.

Response: We appreciate feedback that requiring 50 percent of a group to perform the same activity for the same 90-days may present challenges for large or multi-specialty groups. We believe that requiring at least 50 percent of the group to perform the same activity provides an appropriate balance between requiring at least half of the NPIs reporting as part of a group to participate in the improvement activities performance category and acknowledging the challenges to requiring every NPI in a group to perform the improvement activity for a group to receive credit. However, we do not want to inhibit the clinician's ability to be engaged and fully participate in the selected improvement activity due to scheduling conflicts as noted by commenters. Thus after consideration, we are modifying the proposed policy to balance substantive practice transformation and improved patient outcomes with more flexibility for groups to determine how to implement and perform improvement activities in a way that minimizes disruption to clinical practice, and maintains focus on patient care. Therefore, we are finalizing a modified version of our proposal, such that at least 50 percent of a group's National Provider Identifiers (NPIs) must perform the same activity for any continuous 90 days in the performance period beginning with the 2020 performance year. Instead of requiring clinicians to perform the same activity for the same continuous 90 days, this will allow clinicians flexibility to choose the most appropriate 90-day period while still increasing the number of clinicians required to report. Under the modified policy, a group could choose to perform an activity for the entire performance year to capture the participation of at least 50 percent of the group's clinicians. That is, while 50 percent of NPIs in a group must perform the same improvement activity for a continuous 90-day period, they do not need to perform the activity during the same period. For example, some NPIs could perform ''Practice Improvements for Bilateral Exchange of Patient Information'' (IA_CC_13) during January while others could perform the same activity in June. In that instance, the group attestation would need to reflect the year-long participation. If the clinicians' leave times are staggered, we recommend the clinicians choose different continuous 90-day time periods during the performance year to perform the same improvement activity. In this instance, the group would select activities that may span over the entire performance year to cover all clinicians. We are also revising § 414.1360(a)(2) to reflect this modification.

Comment: Many commenters noted their belief that the proposal could force clinicians to participate in an improvement activity that has no relevance in the field in which they are providing care and recommended that eligible clinicians have the freedom to choose the improvement activities they deem most meaningful. Another commenter recommended setting a percent threshold across the group that allows for variability in activity selection to enable clinicians to choose what is most clinically relevant to them. Other commenters expressed concern that the increased threshold disincentivizes specialties from picking improvement activities which are clinically relevant to them such as when cardiologists in a multispecialty group may not make up 50 percent of the NPIs under the same TIN.

Response: The improvement activities Inventory has been developed to be applicable to broad groups of clinicians. Most improvement activities may be applied to general practice or specialty settings, and therefore, are accessible to groups with large portions of specialty clinicians, or multi-specialty practices. For the CY 2020 MIPS performance period, the improvement activities Inventory will have 20 specialty-specific improvement activities and 85 improvement activities that are broadly applicable to both specialists and general practitioners. We believe that at least 50 percent of a group's eligible clinicians should be able to find applicable improvement activities as we have included broad improvement activities that are not specific to practice size, specialty, or practice setting. For example, the Inventory contains improvement activities that may be applied broadly such as: ''Completion of an Accredited Safety or Quality Improvement Program'' (IA_PSA_28) and ''Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record'' (IA_EPA_1). Regarding the multispecialty group, we believe that specialists should be participating in general improvement activities, as well as activities that are more specialty focused. We are not barring eligible

clinicians from performing additional improvement activities they deem relevant to their specialty; rather, we encourage this to promote practice improvement.

Comment: Many commenters did not support the proposal to increase the threshold to 50 percent of the clinicians in the group to perform the same improvement activity for the same 90-day period because of the interests and burden for multi-specialty groups. Several commenters stated that finding two to four activities that 50 percent of specialists are involved in during the same 90-day period will be difficult, burdensome, onerous to achieve, impractical, and will result in clinicians reporting on a significantly higher number of improvement activities than are required in the improvement activities performance category, and may result in less engagement in improvement activities. A few commenters stated there would be a large administrative burden for multi-specialty groups that are not hospital-based and academic medical groups that consist of multiple specialty and sub-specialties. One commenter noted that the proposal may not be achievable for multi-specialty groups because of scheduling conflicts.

One commenter did not support the proposal because large groups often implement different improvement activities for different types of specialties and the 50 percent threshold would limit the selection of improvement activities to those that could be applied to a broader number of clinicians. The commenter provided an example of a group that develops a program to integrate primary care and mental health services to address ''Integration facilitation and promotion of the colocation of mental health and substance use disorder services in primary and/or non-primary clinical care settings'' (IA_BMH_6) that may involve primary care clinicians and mental health clinicians; however, if primary care and mental health only make up 40 percent of a group, the improvement activity would not ''count'' under the proposal.

One commenter noted the proposal would discourage participation by some clinicians, particularly those in large, multi-specialty groups because clinicians participate in numerous improvement activities which can be expensive and the investment should be recognized by providing credit under the MIPS program. The commenter noted that the investment should be recognized by providing credit under the MIPS program. One commenter noted that other members of the group may not have the time or resources necessary to participate in that activity and that raising the threshold to 50 percent would disincentivize those clinician leaders from participating in the activity, since they would know that there would be no way their group would receive credit.

Another commenter expressed concern about fixing any threshold amount because of varying group composition, size, culture and learning environments; that the improvement activity itself may not be suitable to attaining a fixed threshold; and that applying a fixed threshold will likely increase clinician burden due to the documentation requirement necessary to demonstrate meeting that threshold and recommended if a threshold must be set that consideration be given to something lower than 50 percent, and provided 10 percent as an example.

Response: We appreciate that requiring 50 percent of a group to perform the same activity for the same 90-days may present challenges for large or multi-specialty groups including groups that are not hospital-based and academic groups with multiple specialties and sub-specialties. We refer readers to our modified policy as discussed above, which allows a group more flexibility to complete the activity, such that a group has the entire performance year to ensure that 50 percent of clinicians in the group perform the improvement activity for any continuous 90-days in the performance year. We acknowledge that this policy may cause a minor decrease in flexibility in the improvement activities performance category in regards to the selection of the activity. However, clinicians are able to choose the improvement activity that is most meaningful to their group. Although, we do acknowledge that increasing the group threshold requirement may result in some improvement activities no longer applying for certain practices, the program currently has over 100 improvement activities available and clinicians have flexibility to select ones that are appropriate. In addition, we do not believe that the modified policy will limit the selection of improvement activities to those that could be applied to a broader number of clinicians, as the Inventory was created to be broadly applicable and includes activities that are not specific to practice size, specialty, or practice setting. We encourage practices to perform improvement activities that are relevant to their practice and will demonstrate practice improvements that will be beneficial to their patients. Regarding the comment about a group where only 40 percent of the clinicians where able to participate in the activity; the group would not meet the 50 percent threshold. However, we encourage groups to continue to engage in improvement initiatives that are relevant to their practice. As noted by one commenter, we have a broad Inventory because not every improvement activity will be applicable to every clinician or practice. We appreciate that clinicians take steps to improve their practice and encourage uptake of a range of clinical practice improvements, not all of which will be eligible for credit in the improvement activities performance category, but still result in improved quality of care and improved patient outcomes.

Comment: Many commenters did not support the proposal to increase the threshold to 50 percent and noted that it discourages full participation in the improvement activities performance category as the proposal may increase administrative burden, be impractical, and adds another layer of complexity by altering the policy that clinicians have worked to adhere to. A few commenters did not support the threshold because of the administrative burden of initiating and coordinating widespread adoption of improvement activities and one noted the complexity of tracking adherence in non-employed situations such as with virtual groups and accountable care organizations. Other commenters expressed concerns with the documentation requirements for groups to meet the proposed 50 percent threshold. Another commenter believed that applying a fixed threshold will likely increase clinician burden due to the documentation requirement necessary to demonstrate meeting that threshold and recommended if a threshold must be set that consideration be given to something lower than 50 percent, and provided 10 percent as an example. One commenter noted that a percentage requirement will increase the documentation burden by requiring roll call at meetings and tracking participant's involvement. Another commenter noted that the data collection burden on the group and attestation collection process for the qualified registry or QCDR may be significant. One commenter expressed concern with the increase in the amount of data needed to support that an improvement activity was performed in case of an audit and that duplicative efforts may be needed to provide sufficient evidence in support of larger numbers of clinicians. Other commenters expressed concern that tracking the performance of clinicians

who are part of a TIN structure with a very large number of clinicians, which they stated is typical for academic medical centers, is a monumental task and undermines the purpose of group reporting. One commenter expressed concern that the proposed increase is significant for all groups, regardless of size, and that it increases the burden of documentation and will lead to reduced revenues and additional costs for the eligible clinician or group. One commenter believed the proposal would place further burden upon the dwindling number of independent groups across the country. Another commenter recommended that the proposal should be one of two options, that clinicians could select either: (1) 50 percent of the group performs the same activity; or (2) 75 percent of clinicians in a group could perform multiple activities, each for 90 days.

Response: We do not believe that there will be a significant increase in difficulty in relation to tracking of clinician's participation in a particular improvement activity. We appreciate that there is an increase in administrative tracking of each clinician in a group who performed the improvement activity and the maintenance of maintaining that documentation for audit purposes, but also note that the attestation requirement is the same. We are balancing the increased effort to track clinician performance in a group to meet the 50 percent threshold with the interest in improving quality care and transforming clinical practice; we believe that a 50 percent threshold is an appropriate increase to improve quality care throughout a clinical practice at this time. We also believe that improvement activities are investments in clinical practice and should not be viewed as costs or reduced revenues.

We note that we have not changed our requirements for data submission. It remains as an attestation. We believe more clinicians participating in improvement activities and tracking 50 percent of a group's participation will not significantly increase the effort clinicians will expend to submit attestations to the designated reporting authority. The minor difference from the previous requirement is that the designated reporting authority will be attesting for 50 percent of the group rather than for a single clinician. We do not want to inhibit the clinician's ability to be engaged and fully participate in the selected improvement activity. We believe that our modifications to the proposed policy as discussed previously will enable groups to determine how to implement and perform improvement activities in a way that minimizes any clinical disruption, and maintains focus on patient care.

As discussed in the CY 2020 PFS proposed rule (84 FR 40902), we believe that given groups' familiarity with the improvement activities in the improvement activities Inventory, we believe that a group would find applicable and meaningful activities to complete that are not specific to practice size, specialty, or practice setting and would apply to at least 50 percent of individual MIPS eligible clinicians in the group. Therefore, an increase in the minimum threshold for a group to receive credit for the improvement activities performance category should not present additional complexity or burden. We also anticipate that the vast majority of clinicians performing improvement activities, to comply with existing MIPS policies, would continue to perform the same activities under the policies established in this final rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rule-making (82 FR 54175). Further, as discussed in the 2020 PFS proposed rule (84 FR 40870), we stated that because eligible clinicians attest to improvement activities at the group level, there is no impact on reporting burden as a result of this proposal. Most of the improvement activities in the Inventory remain unchanged for the 2020 MIPS performance period. Of the activities that are being removed or modified many were duplicative which means many clinicians or groups would be able to continue the activity, but it would be reported under a different activity in the improvement activities Inventory. We appreciate the 50 percent group threshold option as one of the commenters' suggestions. We do not believe the other suggestion of requiring 75 percent of the group to perform different activities is appropriate. First, a 75 percent group threshold is a steep increase from the current group reporting threshold of one participant. Second, we believe the group should be performing the same activity in order to facilitate improvement. We anticipate that in future rulemaking, we will continue to increase this threshold. Our future goal would be to have 100 percent of a group performing the same activity during any 90-day period within the same performance year.

Comment: One commenter expressed concern for the unintended consequence of driving organizations toward continually attesting to ''very basic foundational improvement activities'' rather than attempting to perform more focused, difficult, and risk-attendant levels of improvement.

Response: We do not agree that increasing the group threshold reporting threshold to 50 percent will cause groups to choose basic improvement activities. The improvement activities Inventory was created to be broadly applicable and includes activities that are not specific to practice size, specialty, or practice setting. We believe increasing the threshold to at least 50 percent of the clinicians in the group moves the improvement activities performance category towards greater impact and value aligning with the MVP framework. We believe a 50 percent threshold will increase clinician participation, provide for more meaningful clinical practice transformation, and require a level of clinician participation more appropriate for the MVP goal of greater value and impact. We believe the modified final policy will encourage increased clinician participation, provide for more meaningful clinical practice transformation, and will require a level of clinician participation more appropriate for the group to receive credit. We do not believe that it benefits a large group or the patient if only one clinician is undertaking quality improvement efforts because there is not necessarily widespread implementation of the quality initiative.

Comment: One commenter noted the proposed threshold may isolate individual groups from working across medical departments within healthcare settings and noted its impact on preventing clinicians from full participation in facility initiatives.

Response: We disagree that our policy would isolate individual groups from working across medical departments within healthcare settings. The 50 percent group threshold policy is intended for MIPS eligible clinicians who want credit as a group and is not a limitation on clinicians who may be in a particular TIN from participating in any other improvement-related activities outside of MIPS, including those they may be implemented at a facility. Our policy does not restrict clinicians to only participating in activities that improve clinical practice through MIPS. Clinicians may also perform other improvement activities within MIPS should they so desire (but would not receive credit for performing the improvement activity for the group).

Comment: One commenter noted the proposed increase to 50 percent would be particularly burdensome for small practices and recommended that requiring only one clinician to perform an improvement activity for the group to

receive credit should be sufficient for small practices. Another commenter stated the increase is too steep and will jeopardize the ability of clinicians in rural areas to meet the requirements because they will be unable to locate improvement activities for which half their clinicians in their practice can participate in.

Response: We disagree. We believe that this proposal would be easier for a small group to accomplish than a larger group since there will be less clinicians required to complete the activity. We also refer readers to our modification to the proposal discussed above. Instead of requiring clinicians to perform the same activity for the same continuous 90 days, the modified policy will allow clinicians flexibility to choose the most appropriate 90-day period while still increasing the number of clinicians required to report. We believe the modified final policy will encourage increased clinician participation, provide for more meaningful clinical practice transformation, and will require a level of clinician participation more appropriate for the group to receive credit. We do not believe that it benefits a group or the patient if only one clinician is undertaking quality improvement efforts because there is not necessarily widespread implementation of the quality initiative.

We note that we finalized special scoring for small practices for the improvement activities performance category in the CY 2017 Quality Payment Program final rule (81 FR 77185) at § 414.1360 that for MIPS eligible clinicians and groups that are small practices, practices located in rural areas or geographic HPSAs, or non-patient facing MIPS eligible clinicians or groups, to achieve the highest score, one high-weighted or two medium-weighted improvement activities are required. For these MIPS eligible clinicians and groups, to achieve one-half of the highest score, one medium-weighted improvement activity is required. We finalized that small practices, especially those in rural locations and in health professional shortage areas, are required to report only the maximum of two (2) activities in the improvement activities performance category instead of the four (4) required for larger practices. Finally, as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77012) the Small, Underserved, and Rural Support initiative is available to provide free, customized technical assistance to clinicians in small practices. More information regarding the Small, Underserved, and Rural Support initiative may be found on the Quality Payment Program website at *https://qpp.cms.gov/about/small-underserved-rural-practices.*

Comment: One commenter expressed concern that imposing a 50 percent threshold would prevent a group from reporting any of the improvement activities at the group level if reporting through a QCDR. The commenter provided an example of a multi-specialty group comprised of optometrists, retinal specialists, and ophthalmologists which only have four out of ten clinicians reporting through a QCDR due to their scope of clinical practice and availability of relevant QCDR measures.

Response: An eligible clinician should perform improvement activities that are relevant and improve clinical practice whether reporting and submitting as a group or individual aside from the chosen reporting method. The Improvement Activities Inventory includes a broad number of improvement activities that are not only relevant to groups but also to individuals. If an improvement activity is more appropriate for an individual clinician, a group should not be considering it. We include improvement activities that are not only relevant to groups but also to individuals. We believe that improvement activities that are relevant to groups, the 50 percent threshold is most appropriate. We clarify that if clinician groups reporting to a QCDR that do not meet the 50 percent threshold could: (1) Work with the QCDR to have their data submitted for the entire group, not just a subset needed to meet the 50 percent threshold; (2) directly attest to the improvement activity as a group; or (3) submit improvement activities as individuals. No matter which submission method the group decides to utilize the clinicians would still be required to utilize the improvement activities Inventory to choose and complete their activities as QCDRs do not own improvement activities.

Comment: One commenter recommended using a threshold of 50 percent of clinicians in a group who could complete a relevant improvement activity, rather than 50 percent of all clinicians who should complete the activity in the group.

Response: We believe, at a minimum, 50 percent of all clinicians in the group should complete the same activity to facilitate practice improvement. We believe it is impractical to determine who ''could'' complete a particular activity and would add more complexity and burden for a practice to assess and track which clinicians have the ability to complete a specific improvement activity.

Comment: One commenter expressed concern that this proposal does not align with the APM track of the Quality Payment Program because APMs are not held to a similar threshold that takes into consideration how many clinicians within the APM completed the activity.

Response: The improvement activities performance category scoring methodology under the APM scoring standard is designed to reflect the unique statutory and regulatory reporting and scoring requirements and methodologies specific to APM entities (81 FR 77266). While we generally prefer to align scoring standards within MIPS, perfect alignment between the two scoring standards is not always achievable.

Comment: One commenter did not support the proposed policy change and noted their concern that the policy does not contemplate common management structures of specialty groups and departments. The commenter stated that specialty groups often facilitate quality initiatives, data and training through a select few clinical quality leaders or, for larger groups, quality committees. They noted that management structures of groups are often structured with one or a handful of quality champions who must then communicate with and train members of the group on initiatives, goals and best practices in quality improvement. The commenter also noted that we should take these management structures into account when increasing the group threshold. Another commenter expressed concern that implementing a percentage requirement underestimates the role and impact of a lead quality improvement clinician in a group. One commenter recommended clarification for improvement activities which are completed by an organization rather than by an individual clinician because organization-level participation should be taken into account where appropriate. This commenter provided an example of an organization that implements an antimicrobial stewardship program (ASP) which will have an impact on all clinicians in the organization, but that most clinicians will not directly participate in a tangible manner; the commenter believed that all clinicians in the organization are de facto participants in the ASP. A few commenters recommended a differentiation between improvement activities best suited for individual clinician improvement from those that may be applicable to a group quality champion, champions or committee and

that includes documentation requirements.

Response: When crafting a national policy we do consider impacts on clinicians and groups in various management structures and settings. We provide flexibility and choice for selecting improvement activities that are appropriate for the group that are not dependent on management structures. We do not believe that setting a group threshold underestimates the role and impact of the lead quality improvement clinician. Rather, we believe that it provides a minimum standard of group participation and encourages quality improvement actions by more than just one singular clinician. We encourage 100 percent of the clinicians in a group to participate in the quality improvement action and to complete as many improvement activities beyond the minimum 50 percent required by the MIPS program.

We have not provided individual versus group differentiation in the Inventory in the past as we have kept the Inventory broad, thereby allowing clinicians to choose what activities are most relevant to their practice. We will take this comment into consideration as we craft future policies. We provide several resources that may be utilized for assistance with selection of an improvement activity. First, the improvement activities Inventory provides a detailed description of each activity. In addition, we provide resources on the Quality Payment Program website which is available at *https://qpp.cms.gov/.* Finally, the Small, Underserved, and Rural Support initiative is available to provide free, customized technical assistance to clinicians in small practices. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77012), the Small, Underserved, and Rural Support initiative is available to provide free, customized technical assistance to clinicians in small practices. More information regarding the Small, Underserved, and Rural Support initiative may be found on the Quality Payment Program website at *https://qpp.cms.gov/about/small-underserved-rural-practices.* In addition, if clinicians have further questions they may contact the Quality Payment Program service center at *QPP@cms.hhs.gov* or at 1–866–288–8292.

Comment: Several commenters did not support the proposed increase and noted that it does not reflects the realities of clinical practice. These commenters stated that a specific improvement activity might be applicable to only one or two clinicians, but still have the capacity to vastly improve and impact a large portion of the group's patients. A few commenters requested clarification on how credit would be applied to groups in a scenario when a small subset of a group's clinicians cover extended hours for all of the clinic's patients, but patient access improves for the entire population served. One commenter referenced an example in which a group hires an additional fulltime clinician to extend office hours; the group as a whole invested in a new clinician to increase its availability to its patients and should be recognized as such. Another commenter provided an example in which a clinic extended its hours for all of the clinic's patients, regardless of the percentage of clinicians who work the extended hours, and questioned how a group with 20 clinicians would receive improvement activities credit.

Response: We do understand the realities of clinical practice and believe that improvement activities are broadly applicable. While we understand that one clinician completing an activity may have benefits, we do not believe that only one clinician completing an activity would necessarily create a widespread benefit for an entire group. While in some small groups, one participant may have a greater impact, for larger groups, one participant is a very low bar. We do not agree the commenter's example of hiring an additional full time clinician to extend office hours demonstrates group level improvement. For example, to demonstrate meaningful practice improvement for an improvement activity like ''Provide 24/7 access to eligible clinicians or groups who have real-time access to patient's medical record'' (IA_EPA_1), under our modified policy discussed above, the group could utilize 5 out of the 20 clinicians for one continuous 90-day performance period and another 5 clinicians for an additional continuous 90-day performance period. In this example, the group could achieve the 90-day threshold while providing increased access to their patients. We encourage individual clinicians to perform improvement activities that impact the entire group.

After consideration of the comments, we are finalizing our proposal with modification, such that instead of requiring that a group must perform the same activity for the same continuous 90 days in the performance period as proposed, we are requiring that a group must perform the same activity during any continuous 90-day period within the same performance year. Therefore, we are revising § 414.1360(a)(2) to state that beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.

(e) Improvement Activities Inventory

In the CY 2020 PFS proposed rule (84 FR 40764 through 40765), in this final rule we are finalizing changes to the improvement activities Inventory: (1) Establishing removal factors to consider when proposing to remove improvement activities from the Inventory; (2) removing 15 improvement activities for the 2020 performance period and future years contingent on our proposed removal factors being finalized; (3) modifying seven existing improvement activities for the 2020 performance period and future years; and (4) adding two new improvement activities for the 2020 performance period and future years. These are discussed in more detail in this final rule.

(i) Factors for Consideration in Removing Improvement Activities

In the CY 2017 Quality Payment Program final rule (82 FR 53660 through 53661), we discussed that in future years, we anticipated developing a process and establishing factors for identifying improvement activities for removal from the improvement activities Inventory through the Annual Call for Activities process. In the CY 2018 Quality Payment Program proposed rule (82 FR 30056), we invited public comments on what criteria should be used to identify improvement activities for removal from the Inventory. A few commenters did not support the idea of establishing removal factors for improvement activities, believing that many groups have made financial investments to perform these improvement activities and that no activities should be removed. Some commenters suggested that we should remove improvement activities that: Have become obsolete, are topped out, do not show demonstrated improvements over time, or are not attested to for three consecutive years. The commenters recommended that their removal should be conducted using an approach similar to what is used for the removal of quality measures. In our responses, we stated

that we appreciate the commenters input. In addition, we understand that many groups may have made financial investments to perform these improvement activities, but believe that over time, certain improvement activities should be considered for removal to ensure the list is robust and relevant. We will fully examine each activity prior to removal. In addition, we stated that commenters would have an opportunity to provide their input during notice-and-comment rulemaking. We agreed with commenters that we should remove improvement activities as needed and should consider the removal criteria already established for quality measures. We continue to believe that having factors to consider in removing improvement activities would provide transparency and alignment with the removal of quality measures. Therefore, we proposed to adopt the following factors for our consideration when proposing the removal of an improvement activity:

- *Factor 1:* Activity is duplicative of another activity;
- *Factor 2:* There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice;
- *Factor 3:* Activity does not align with current clinical guidelines or practice;
- *Factor 4:* Activity does not align with at least one meaningful measures area;
- *Factor 5:* Activity does not align with the quality, cost, or Promoting Interoperability performance categories;
- *Factor 6:* There have been no attestations of the activity for 3 consecutive years; or
- *Factor 7:* Activity is obsolete.

These factors directly reflect those already finalized for quality measures found in the CY 2019 PFS final rule (83 FR 59765). The removal of improvement activities from the Inventory, including discussion of the removal factor(s) considered, will occur through notice-and-comment rulemaking. We note that these removal factors are considerations taken into account when deciding whether or not to remove improvement activities; but they are not firm requirements.

Therefore, we invited public comments on our proposal to implement factors to consider in removing improvement activities from the Inventory. In conjunction with this proposal, we proposed a number of improvement activity removals as discussed in the next section and in Appendix 2 of this final rule. Those removals are contingent upon finalization of these removal factors.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the establishment of seven factors for consideration on whether to remove particular improvement activities from improvement activities Inventory because they believed that the criteria are well aligned with the agency's Meaningful Measures framework and would help promote the inclusion of activities that have a meaningful link to better quality of care. One commenter supported the effort to align criteria for improvement activity removal with quality measure removal criteria. One commenter supported the seven factors and particularly the removal of improvement activities that may be duplicative.

Response: We agree and appreciate the commenter's support.

Comment: One commenter supported the proposed removal factor 3. Another commenter stated that they appreciate our efforts to align criteria for improvement activity removal with quality measure removal criteria. The commenter requested clarification of our interpretation of the final criteria and the use of the word ''obsolete.''

Response: We consider an activity ''obsolete'' when it is no longer available, and therefore, cannot be completed by eligible clinicians as an improvement activity. For example, in Appendix 2 of this final rule we are finalizing the removal of ''TCPI Participation'' (IA_CC_4) under removal factor 7. This improvement activity is obsolete because the Transforming Clinical Practice Initiative (TCPI) ended on September 28, 2019 and clinicians are no longer able to attest to this improvement activity.

Comment: A few commenters expressed concerns that we are removing improvement activities from the MIPS program too rapidly and limiting clinician choice. A few commenters expressed concerns that many groups have made financial investments to perform a particular improvement activity and that removal of improvement activities could jeopardize the group's return on that investment while requiring new program costs. One commenter recommended that we be judicious in the removal of improvement activities. One commenter recommended that no activities should be removed from the list unless they are obsolete, such as activities that require participating in a program that no longer exists. One commenter noted that the trend toward measure consolidation and activity removal seen now in both the improvement activities and the quality performance category will prove limiting to clinicians. This commenter noted that we should ensure that clinicians can continue to tailor improvements to their practice and not unintentionally limit practices by over-pruning the improvement activities and measures of the MIPS program because improvement cannot and should not become a one-size-fits-all process. One commenter did not support removing improvement activities from the improvement activities Inventory stating it is contrary to the intent of the improvement activities performance category and recommended a judicious approach to the removal process and that the improvement activities performance category should support the performance of any improvement activity that improves patient care. This commenter noted that a policy that removes activities from the improvement activities Inventory would stymie this goal, suggesting that groups should only implement temporary rather than long-term changes and that removing activities could harm groups and patients, particularly those in small and rural practices, which often have limited financial and personnel resources.

Response: We do not believe we are removing improvement activities too rapidly. We have been judicious in our proposals to remove activities in line with the removal criteria we have proposed. We agree that practice improvement should not be a one-size-fits-all process. We intend to keep the improvement activities Inventory as broad as appropriate to allow clinicians to apply the improvement activities in a clinically relevant and meaningful manner. We believe to ensure that the improvement activities Inventory stays relevant and robust, it is essential to establish removal criteria. We continue to believe that having factors to consider in removing improvement activities would provide transparency and alignment with the removal of quality measures. We are not suggesting that groups should only implement temporary improvements, to the contrary, we encourage long term improvements in clinical practices. We do not believe that removing activities could harm groups and patients, particularly those in small and rural practices. We encourage clinicians across all practice sizes, including small and rural practices, to continue to perform quality initiatives that facilitate the delivery of high quality care, help transform clinical practice and are in the best interest of patient care the best

interest of patient care. We understand that many groups may have made financial investments to perform these improvement activities, but believe that over time, certain improvement activities should be considered for removal to ensure the list is robust and relevant. We will fully examine each activity prior to removal. In addition, commenters would have an opportunity to provide their input during notice-and-comment rulemaking.

Comment: A few commenters did not support factor 5 that provides for the removal of an activity that does not align with the quality, cost, or Promoting Interoperability performance categories, because the improvement activities performance category should allow for innovation. A few commenters stated that factor 5 could increase the burden on clinicians by limiting improvement activities related to their scope of practice. One commenter noted that the purpose of the improvement activities performance category is to provide credit to clinicians for work towards improving care and that factor 5 would constrain the development and inclusion of potentially innovative activities because they do not align with the other three performance categories. One commenter recommended delaying factor 5 until the MVPs have been finalized, implemented, and assessed.

Response: The improvement activities performance category supports innovation, as well as activities that go beyond the standard of care. We do not believe that aligning the performance categories will limit activities related to a clinician's scope of practice as the activities within the Inventory were created to be broad and are not specific to practice size, specialty, or practice setting. In addition, we do not believe we should delay implementing factor 5 as we believe it is important for improvement activities to align with the other performance categories in order to provide a more cohesive program and must make an effort to move in that direction. As discussed in the CY 2020 PFS proposed rule (84 FR 40732 through 40733), we provided an overview of the MVP framework for future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year to simplify MIPS, improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians. We agree that the MIPS program encourages clinicians to pursue measures and activities that improve care. We also believe that it is imperative that we streamline the program through the creation of the MVPs. To have one cohesive program, we intend to align all of the performance categories to create the MVPs. Therefore, we believe that removal factor 5 should be a consideration when removing improvement activities from the MIPS program to lay the groundwork for MVPs. We refer readers to section III.k.3.a. of this final rule for further discussions on the MVP framework.

Comment: A few commenters expressed concerns with factor 1. One commenter recommended that we be judicious in the removal of improvement activities, particularly if utilizing the proposed ''duplicative'' criteria. One commenter noted that some improvement activities may appear, similar on the surface, but may be implemented differently in various clinical settings and encouraged us to consider specific ways in which seemingly ''duplicative'' activities are actually utilized in the various clinical settings. One commenter cautioned removing too many ''duplicative'' improvement activities from the list without ensuring that the corresponding remaining activity does not require clinicians to perform more work than in the ''duplicative'' one.

Response: We appreciate the commenters' support. We want to assure stakeholders that we have and will continue to fully examine each activity prior to proposing to remove the improvement activity. As discussed above, the removal of an improvement activity from the Inventory, including discussion of the removal factor(s) considered, will occur through notice-and-comment rulemaking. Therefore, commenters will have an opportunity to provide their input during the notice-and-comment rulemaking process.

After consideration of the comments, we are finalizing our proposal, as proposed, to adopt the seven factors discussed above, for our consideration when proposing the removal of an improvement activity.

(ii) New Improvement Activities and Modifications to and Removal of Existing Improvement Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would add new improvement activities or modifications to existing improvement activities to the improvement activities Inventory through notice-and-comment rulemaking. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), and Tables X and G in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303) for our previously finalized improvement activities Inventory. We also refer readers to the Quality Payment Program website at *https://qpp.cms.gov/* for a complete list of the most current list of improvement activities. In this final rule, we are: (1) Removing 15 improvement activities from the Inventory beginning with the 2020 performance period, (2) modifying seven existing improvement activities for 2020 performance period and future years, and (3) adding two new improvement activities for 2020 performance period and future years. We refer readers to Appendix 2 of this final rule for further details. Our improvement activities removals are made in conjunction with our adoption of removal factors.

(f) CMS Study on Factors Associated With Reporting Quality Measures

In this final rule, we are finalizing our proposal to end this study and concurrently, remove the incentive under the improvement activity performance category that this study provided for study participants.

(i) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77195), we created the Study on Improvement Activities and Measurement. In our quest to create a culture of improvement using evidence-based medicine on a consistent basis, we believe fully understanding the strengths and limitations of the current processes of collecting and submitting quality measurement data is crucial to better understand and improve these current processes. We proposed to conduct a study on clinical improvement activities and measurement to examine clinical quality workflows and data capture using a simpler approach to quality measures (81 FR 77195). In the CY 2018 Quality Payment Program final rule (82 FR 53662) and CY 2019 PFS final rule (83 FR 59783), we finalized updates to the study.

Starting in CY 2017, this annual study was slated for a minimum period of 3 years, as stated in CY 2019 PFS final rule (83 FR 59776). Study participants were recruited every study year. The study population started in CY 2017 with a minimum of 42 individuals (81 FR 77195), grew to a minimum of 102 individuals for CY 2018 (82 FR 53662) and 200 individuals for CY 2019 (83 FR 59783). Each years' study population is comprised of the following categories: Urban versus non-urban, groups and individual clinicians; clinicians

reporting quality measures in groups or reporting individually, different practice sizes; and different specialty groups (81 FR 77195). These changes to the study sample size over the years provided data for the study's analysis. The goals of the study are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians desiring: A more data driven approach to quality measurement, measure selection unconstrained by a CEHRT program or system, improving data quality submitted to CMS, enabling CMS get data more frequently and provide feedback more often (81 FR 77195). To encourage participation by clinicians and counterbalance clinician burden for anticipation of study, participating clinicians were incentivized with full improvement activity credit as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77195 through 77197).

(ii) Study End and Removal

We believe by the end of 2020 we will have reached the minimum sample size and have accrued the minimum data needed for the analysis to achieve the study goals. Therefore, in the CY 2020 PFS proposed rule (84 FR 40765), we proposed to conclude this study at the end of the CY 2019 performance period. In conjunction with our proposal to end the study, we also proposed to remove the study and the incentive provided towards the improvement activity performance category beginning with the 2020 performance period because it would be obsolete (removal factor 7). As a result, the full improvement activity credit given to participants as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77195 through 77197), would no longer be available starting with the 2020 performance period.

The following is a summary of the comments we received and our responses.

Comment: A few commenters encouraged us to continue to seek ways to incentivize clinician organizations and vendors to participate in measure or program development to ensure true quality measurement and improvement. One commenter supported that this study has reached its statutory requirements; recommended that the results and the data be made publicly available once analysis is complete in Spring 2020; and encouraged us to conduct similar studies in future years as the program evolves. One commenter recommended that we should be continuously evaluating measures and improvement activities especially as the MIPS program progresses and requirements become more stringent.

Response: We refer readers to subsection ''(iii) Future Steps'' below where we discuss our plans to make the study results and recommendations available to the public. We also plan to continue to pursue ways to improve outcomes, reduce burden in the collection and reporting of clinician quality measures, and enhance clinical care. We continue to utilize the Blueprint for the CMS Measures Management System and stakeholder input to continuously maintain and improve our measures to meet the requirements and standards of MIPS.

After consideration of the comments, we are finalizing our proposal, as proposed, to conclude this study at the end of the CY 2019 performance period and to remove the study and the incentive provided towards the improvement activity performance category beginning with the 2020 performance period under removal factor 7.

(iii) Future Steps

After completing this data collection phase, we next plan to analyze the data gathered (which include lessons learned) and to make recommendations to improve outcomes, reduce burden, and enhance clinical care. We plan to finish the final data analysis by spring 2020. This analysis would contain all the study years. It would show the trends and associations of all the factors we examined. It would also show the lessons learned by study participants over the 3 years of the study. At the conclusion of this study and after analysis of the results, we plan to shift our focus to implementation of recommendations. We intend for this to include feedback to clinicians and stakeholders and educational and outreach work. We plan to undertake education and outreach to the public. We would also include the results in other Quality Payment Program educational materials such as webinars.

(4) Promoting Interoperability

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of Certified Electronic Health Record Technology (CEHRT) as a performance category under the MIPS. In prior rulemaking, we referred to this performance category as the Advancing Care Information performance category, and it was reported by MIPS eligible clinicians as part of the overall MIPS program. In 2018, we renamed the Advancing Care Information performance category as the Promoting Interoperability performance category (83 FR 35912). As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the Promoting Interoperability performance category.

For the Promoting Interoperability performance category, our proposals included (84 FR 40766 through 84 FR 40784): (1) For the 2023 MIPS payment year, establishing a performance period of a minimum of a continuous 90-day period within CY 2021, up to and including the full calendar year; (2) making the Query of Prescription Drug Monitoring Program (PDMP) measure optional in CY 2020, and in the event we finalize this proposal, making the e-Prescribing measure worth up to 10 points in CY 2020; (3) removing the numerator and denominator for the Query of PDMP measure and instead requiring a ''yes/no'' response beginning in CY 2019; (4) removing the Verify Opioid Treatment Agreement measure beginning in CY 2020; (5) redistributing the points for the Support Electronic Referral Loops by Sending Health Information measure to the Provide Patients Access to Their Health Information measure if an exclusion is claimed, beginning in CY 2019; (6) revising the description of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure exclusion to more clearly and precisely capture our intended policy, beginning in CY 2019; (7) continuing the existing policy of reweighting the Promoting Interoperability performance category for certain types of nonphysician practitioner (NPP) MIPS eligible clinicians for the performance period in 2020; and (8) proposals related to hospital-based MIPS eligible clinicians and non-patient facing MIPS eligible clinicians in groups.

(b) Goals of Changes to the Promoting Interoperability Performance Category

As we look toward the future of the Promoting Interoperability performance category, the general goals of the policies that we are adopting in this final rule center on: (1) A priority of stability within the performance category after the recent changes made in the CY 2019 PFS final rule (83 FR 59785 through 59820) while continuing to further interoperability through the use of CEHRT; (2) reducing administrative burden; (3) continued use of 2015 Edition CEHRT; (4) improving patient access to their health

information so they can make fully informed health care decisions; and (5) continued alignment with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, where appropriate.

(c) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2019 PFS final rule at § 414.1320(e)(1) (83 FR 59745 through 59747), for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within CY 2020, up to and including the full CY 2020 (January 1, 2020 through December 31, 2020).

For the 2023 MIPS payment year, we proposed to add § 414.1320(f)(1), which would establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year (CY 2021) (84 FR 40766). This proposal aligned with the proposed EHR reporting period in CY 2021 for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs (84 FR 19554 through 19555). We stated that we believe this would be an appropriate performance period because of the maturation needed within the performance category, including the changes to measures and other changes being proposed in this rule. In addition, it would offer stability and continuity for the Promoting Interoperability performance category after the performance category overhaul that was finalized in the CY 2019 PFS final rule (83 FR 59785 through 59820).

We requested public comments on this proposal, and the following is a summary of the comments we received and our responses.

Comment: Many commenters supported the minimum of a continuous 90-day performance period that occurs 2 years prior to the applicable MIPS payment year. Commenters stated that the proposed performance period would allow MIPS eligible clinicians to adequately plan for any system updates and that it reduces administrative and regulatory burden. Several commenters also expressed their appreciation toward CMS for its efforts, including the proposed 90-day performance period, to help stabilize the Promoting Interoperability performance category.

Response: We agree that keeping the performance period to a minimum of 90 consecutive days affords MIPS eligible clinicians the flexibility they may need to develop and update their evolving EHRs.

Comment: Some commenters suggested that CMS should make the minimum 90-day performance period permanent, as opposed to what CMS has done over the past several years, which is to propose the minimum 90-day performance period each year.

Response: We thank the commenter for the suggestion, and we may take this into consideration for future rulemaking. We are still in the initial years of implementing the Promoting Interoperability performance category after our overhaul and we believe it is important to maintain flexibility as we gain experience so that we can evaluate and determine whether adjustments are needed.

Comment: One commenter asked if the proposed performance period would require reporting on all patients during the 90-day period, or if this is an option being added within the full calendar year.

Response: For the 2023 MIPS payment year, a MIPS eligible clinician would have to select and report data for patients from any continuous 90-day period, at a minimum, within CY 2021. The MIPS eligible clinician may choose to report data from a period longer than 90 consecutive days, up to and including the full CY 2021.

After consideration of the public comments we received, for the 2023 MIPS payment year, we are finalizing the proposal to add § 414.1320(f)(1) and establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year (CY 2021).

(d) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Changes to Measures for the e-Prescribing Objective

(A) Background

Beginning with the performance period in CY 2019, we adopted two new measures for the e-Prescribing objective that are based on electronic prescriptions for controlled substances: (1) Query of Prescription Drug Monitoring Program (PDMP) (83 FR 59800 through 59803); and (2) Verify Opioid Treatment Agreement (83 FR 59803 through 59806). During the comment period for the CY 2019 PFS proposed rule (83 FR 35921 through 35925), we received extensive comments from stakeholders regarding the Query of PDMP measure and the Verify Opioid Treatment Agreement measure. While this feedback was the main catalyst for our proposals, we noted in the CY 2020 PFS proposed rule (84 FR 40766 through 40769) that there have also been significant legislative changes that have the potential to positively impact the Promoting Interoperability performance category, specifically the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018). While this legislation was not the main reason for our proposals, we stated that we believe it may significantly affect the maturation, requirements, and use of PDMPs and state networks upon which the Query of PDMP measure is dependent.

(B) Query of Prescription Drug Monitoring Program (PDMP) Measure

As discussed in the CY 2020 PFS proposed rule (84 FR 40766 through 40769), we proposed to make the Query of PDMP measure optional and eligible for 5 bonus points for the e-Prescribing objective in CY 2020. Making the measure optional in CY 2020 would allow time for further integration of PDMPs and EHRs to minimize the burden on MIPS eligible clinicians reporting this measure while still giving clinicians an opportunity to report on and earn points for the measure. We proposed that, in the event we finalize this proposal for the Query of PDMP measure, the e-Prescribing measure would be worth up to 10 points in CY 2020.

In addition, beginning with the CY 2019 performance period, we proposed to remove the numerator and denominator established for the Query of PDMP measure in the CY 2019 PFS final rule (83 FR 59800 through 59803), and instead require a ''yes/no'' attestation response. A ''yes'' response would indicate that for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician then used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.

We invited public comments on these proposals, and the following is a summary of the comments we received and our responses.

Comment: A majority of commenters supported the proposed changes to the Query of PDMP measure and agreed with the measure remaining optional in CY 2020. One commenter further recommended that in the future, regardless of whether the measure is optional or required, HHS' Office of the National Coordinator for Health Information Technology (ONC) should consider adopting new certification criteria requiring EHRs to integrate with PDMPs. Commenters also agreed with changing the measure to a ''yes/no'' attestation response rather than reporting a numerator and denominator. Commenters indicated that these changes would reduce unnecessary burden, as developing custom reports can often be time-consuming and inaccurate.

Response: We believe this proposal would help reduce overall clinician burden by eliminating the need for clinicians to manually track the number of times that they query a PDMP outside of CEHRT functionality. We recognize there is currently limited standardization of interfaces between CEHRT technology and PDMPs, and we will continue to collaborate with ONC to explore how the ONC certification program could support PDMP–EHR integration in the future. We note that PDMP–EHR integration may refer to varying approaches for the access and viewing of PDMP data from an EHR and is used to refer, as well to the incorporation of the PDMP data into the EHR record. For more information on relevant standards we refer readers to the ONC Interoperability Standards Advisory (see *https://www.healthit.gov/isa/allows-a-prescriber-request-a-patients-medication-history-a-state-prescription-drug-monitoring* and *https://www.healthit.gov/isa/allows-exchange-state-prescription-drug-monitoring-program-pdmp-data*).

Comment: One commenter stated that in the CY 2020 PFS proposed rule (84 FR 40771 through 40775) Table 41: Objectives and Measures for the Promoting Interoperability Performance Category in 2020, there is no exclusion information for the Query of PDMP measure and sought clarification on whether the Query of PDMP measure offers any exclusions. More specifically, given that some clinicians do not prescribe Schedule II controlled substances, how should they respond if the measure would require a ''yes/no'' response?

Response: As stated in the CY 2019 PFS proposed rule period (83 FR 59800 through 59803), we did not provide exclusions for the Query of PDMP measure as it was optional and eligible for bonus points. We still do not believe that exclusions would be necessary for the Query of PDMP measure if it is to remain optional and eligible for bonus points in CY 2020. Eligible clinicians who choose not to report on the optional measure may still earn a score for the Promoting Interoperability performance category.

Comment: One commenter stated that they believe the Query of PDMP measure should not be optional given that they have been able to successfully standardize queries into their patient-centered clinical programs. While they agree that challenges and variations between states are real, their opinion is that it is not insurmountable and that maintaining strong PDMP incentives would help drive much needed improvements.

Response: We appreciate the commenter's effort to operationalize this measure into their workflow; however, the majority of stakeholder feedback that implementing and calculating this measure can impose significant burden on clinicians and should not be a required measure. In addition, we received substantial feedback from commenters, health IT vendors, and specialty societies that the flexibility within the numerator and denominator calculations finalized in the CY 2019 PFS final rule (83 FR 59800 through 59803) presents unintended challenges, such as the significant burden associated with IT system design and development needed to accommodate the measure and any future changes to it.

Comment: One commenter questioned whether the query of the PDMP must be performed by the same eligible clinician or health care professional who prescribes the Schedule II opioid.

Response: We do not require the query of the PDMP be performed by the same eligible clinician who prescribes the Schedule II opioid. We believe that MIPS eligible clinicians should determine what is most appropriate, in accordance with applicable law, for the medical staff involved in performing the queries based on their own standard operating procedures, guidelines, and preferences.

Comment: One commenter shared concerns that a ''yes/no'' optional measure may diminish overall reporting, thus undermining an essential component in addressing the current opioid epidemic.

Response: We understand such concerns and appreciate the feedback. However, specifically regarding the Query of PDMP measure, we believe it is premature for this activity to be assessed with a numerator/denominator as part of a performance-based measure. At the present time, with limited use of consistent standards-based approaches to supporting the integration between CEHRT and state PDMPs, this contributes to MIPS eligible clinicians having to manually track each individual query. Considering the added burden that doing so creates, we believe a ''yes/no'' response is more appropriate.

Comment: Some commenters expressed concerns with the PDMP measure due to varying privacy or security protocols in place, as well as other related aspects lacking uniformity in the implementation of independent PDMPs across state lines. Given that there are limited formalized, standard criteria for PDMP functionality, commenters stated that the measure is still not ready for mandatory inclusion in the Promoting Interoperability performance category. Another commenter recommended that the PDMP measure be considered optional for reporting in CY 2021 as well.

Response: We understand that PDMP systems are composed of various processes and components that vary significantly across state lines, and that in any given state the PDMP system may include a variety of state-developed and vendor-based solutions along with the core PDMP database. State laws and policies also differ on data storage, use, access roles, disclosures, and key definitions. The degree of PDMP and health IT access integration (how the provider can access the PMDP) may vary significantly across states, as well as within states by product or health system. Today, it is our understanding that most PDMP systems allow a provider ''view only'' access to PDMP data rather than allowing for the seamless integration of discrete data from the PDMP system into a patient's record.

The SUPPORT Act includes new requirements and federal funding for PDMP enhancement, integration, and interoperability, and establishes mandatory use of PDMPs by certain Medicaid providers. We are continuously working with various stakeholders and ONC to evaluate the implementation of the SUPPORT Act, as well as its related progress around furthering PDMP–EHR integration.

We proposed to change the measure to optional in CY 2020 to account for readiness concerns such as those raised

by stakeholders. We are dedicated to alleviating the concerns as we work to further develop the measure. We have not made a proposal with regard to the measure's status for CY 2021.

After consideration of the public comments we received, we are finalizing the proposal to make the Query of PDMP measure optional and eligible for 5 bonus points for the Electronic Prescribing objective in CY 2020. Given that we are finalizing this proposal for the Query of PDMP measure, we are also finalizing the proposal that the e-Prescribing measure will be worth up to 10 points in CY 2020. Lastly, we are finalizing the proposal to remove the numerator and denominator previously established for the Query of PDMP measure in the CY 2019 PFS final rule (83 FR 59800 through 59803) and instead require a ''yes/no'' response beginning with the 2019 performance period.

We will continue to work to improve EHR integration with PDMPs as we believe that making the Query of PDMP measure optional for the long-term would be inconsistent with the recommendations of the President's Opioid Commission (*https://www.whitehouse.gov/wp-content/uploads/2019/05/Opioid-Commission-Report-One-Year-Later-20190507.pdf*). We may propose modifications to this measure in future rulemaking.

(B) Verify Opioid Treatment Agreement Measure

In the CY 2019 PFS final rule (83 FR 59803 through 59806), we finalized the Verify Opioid Treatment Agreement measure as optional in both CYs 2019 and 2020. Since we proposed this measure, we have heard from stakeholders that this measure has presented significant implementation challenges and an increase in burden, and does not further interoperability. Stakeholders have indicated that the measure is vague, burdensome to measure, and does not necessarily offer high clinical value to health care providers or support the clinical goal of supporting OUD treatment. For the reasons discussed in the proposed rule (84 FR 40769), we proposed to remove the Verify Opioid Treatment Agreement measure from the Promoting Interoperability performance category beginning with the performance period in CY 2020.

We invited public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters were in general agreement with removing the Verify Opioid Treatment Agreement measure. Several commenters stated that if the measure were to remain, it would result in increased provider burden and decreased interoperability. One commenter supported removing the measure at least until treatment agreement standards themselves are addressed, clarified, and adequately piloted by CMS or ONC. Other commenters further stated their belief that this measure lacks standards defining specific data points and structure to be included in a treatment agreement. One commenter who supported the measure's removal indicated that the decision over whether to use opioid treatment agreements (as part of the physician-patient treatment relationship) should be left solely to the clinical judgment of individual attending physicians.

Response: While we agree that while addressing OUD prevention and treatment is essential, we believe that the Verify Opioid Treatment Agreement measure presents significant implementation challenges, leads to increases in burden, and does not promote interoperability. We appreciate the commenter's suggestion of conducting a pilot of treatment agreement standards and we may consider this in the future. We appreciate the suggestions on how to enhance and improve such a measure as we continue to combat the opioid crisis. We do acknowledge that there is not consensus regarding whether opioid treatment agreements should be required and whether they should be considered a potential component of the physician-patient treatment relationship.

Comment: A few commenters requested that the measure remain optional for CY 2020 instead of being removed. They suggested this would provide the measure extra time for new, clarifying guidance to be formulated in regards to the measure's future expectations. An additional commenter similarly requested confirmation on whether the measure's scoring component would remain a numerator/denominator calculation or if it would be changed to a ''yes/no'' attestation response.

Response: We appreciate the concerns and suggestions addressed by the commenters who believe the Verify Opioid Treatment Agreement measure should remain optional in CY 2020. However, we disagree that the Verify Opioid Treatment Agreement measure should remain an optional measure with bonus points through CY 2020 given the strong provider community feedback, including reasons noted in this section such as the lack of standards or concrete program-wide definitions. While a commenter requested changing the measure to a yes/no attestation for CY 2019, we have decided that the measure will remain an optional, numerator/denominator-based measure in CY 2019 only.

Comment: Some commenters agreed that an opioid-specific measure is important in addressing the current epidemic, but stated that the Verify Opioid Treatment Agreement measure should be removed while simultaneously encouraging innovation through a future collaborative measure development process. The commenters indicated that this measure is burdensome and vague, presenting significant implementation challenges as it is easily subject to misinterpretation until clear certification requirements are formally established.

Response: We agree with the commenters who stated that the measure is vague which causes implementation challenges. Additionally, the lack of certification criteria and standards may result different interpretations by vendors which may limit interoperability. We appreciate the support in the removal of this measure.

After consideration of the public comments we received, we are finalizing the proposal to remove the Verify Opioid Treatment Agreement measure from the Promoting Interoperability performance category beginning with the performance period in CY 2020.

(ii) Health Information Exchange Objective

(A) Modification of the Support Electronic Referral Loops by Sending Health Information Measure

In the CY 2019 PFS final rule (83 FR 59807 through 59808), we renamed the Send a Summary of Care measure to the Support Electronic Referral Loops by Sending Health Information measure. Although an exclusion is available for this measure (83 FR 59808), we acknowledged that we did not address in the CY 2019 PFS proposed rule how the points for the measure would be redistributed in the event that an exclusion is claimed, and stated that we intended to propose a redistribution policy in this year's rulemaking (83 FR 59795). Accordingly, in the CY 2020 PFS proposed rule, we proposed to redistribute the 20 points associated with the Support Electronic Referral Loops by Sending Health Information measure to the Provide Patients

Electronic Access to Their Health Information measure if an exclusion is claimed (84 FR 40770). We further stated in the proposed rule that if exclusions are claimed for both the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and the Support Electronic Referral Loops by Sending Health Information measure, the combined 40 points associated with both measures would be redistributed to the Provide Patients Electronic Access to Their Health Information measure. Lastly, we proposed that this redistribution policy would be applicable starting with the 2019 performance period/2021 MIPS payment year.

We received public comments on our proposals and the following is a summary of the comments we received and our responses.

Comment: A majority of commenters fully supported our proposals for point redistribution when an exclusion is claimed for one or both of these measures.

Response: We appreciate the overwhelming support and agree that our proposed approach to point redistribution is appropriate.

Comment: One commenter did not fully agree with redistributing all 40 points from both measures to the Provide Patients Electronic Access to Their Health Information measure. The commenter stated that this would place too much weight on a measure that has been required for years.

Response: We believe that many MIPS eligible clinicians may be eligible to claim exclusions for both the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and the Support Electronic Referral Loops by Sending Health Information measure. With this, we have chosen to redistribute the points to the Provide Patients Electronic Access to their Health Information measure. We believe that the emphasis placed on the Provide Patients Electronic Access to their Health Information measure through the redistribution of points reflects our emphasis on patient engagement in their health care and patient's electronic access of their health information through the use of APIs.

Comment: One commenter did not support this proposal stating that this redistribution pattern could provide an unfair advantage to smaller organizations that claim the exclusion, leading to overall skewed scoring.

Response: We disagree, and believe redistributing the points to the Provide Patients Electronic Access to their Health Information measure emphasizes improved electronic access to patient health information and allows for health IT solutions that encourage adoption and innovation in the use of CEHRT.

After consideration of the public comments we received, we are finalizing the proposal to redistribute the 20 points associated with the Support Electronic Referral Loops by Sending Health Information measure to the Provide Patients Electronic Access to Their Health Information measure if an exclusion is claimed. Furthermore, if exclusions are claimed for both the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and the Support Electronic Referral Loops by Sending Health Information measure, the combined 40 points associated with both measures will be redistributed to the Provide Patients Electronic Access to Their Health Information measure. Lastly, we are finalizing the proposal that this redistribution policy is applicable starting with the 2019 performance period/2021 MIPS payment year.

(B) Modification of the Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

In the CY 2019 PFS final rule (83 FR 59808 through 59812), we replaced the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure with a new measure called the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. Additionally, we established the following exclusion for the new measure at that time: Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period would be excluded from this measure (83 FR 59812). In the CY 2020 PFS proposed rule (84 FR 40770), we proposed to revise the description of this exclusion to more clearly and precisely capture our intended policy, to reads as follows: Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period. We proposed that the revised description of the exclusion would be applicable beginning with the 2019 performance period/2021 MIPS payment year.

We received public comments on our proposal and the following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to revise the description of the exclusion, stating that the original verbiage was difficult to interpret.

Response: We agree with the commenters that revising the description of this exclusion would help to reduce any potential confusion or misinterpretation.

Comment: Many commenters did not support the proposal to revise the description of the exclusion, stating that it would be more difficult to meet the exclusion criteria than under the previously established language.

Response: We appreciate the commenters' feedback and respectfully disagree. As we noted in the PFS proposed rule (84 FR 40770), the description of the exclusion that we included in the CY 2019 PFS final rule (83 FR 59812) could be construed in a way that would make the exclusion more difficult for a MIPS eligible clinician to meet. Specifically, it could be read to create two different sets of exclusion criteria, which was not our intention. Our proposal simply reflects our intention to retain the same exclusion from the Request/Accept Summary of Care measure.

Comment: Several commenters did not support the proposal to revise the description of the exclusion, stating that eligible clinicians who do not receive a summary of care are unable to report on the measure, thereby receiving a denominator of zero, by no fault of their own.

Response: We appreciate the comments and concerns submitted by the commenters. If a clinician does not receive any summaries of care, the clinician may be eligible to claim the exclusion. If the exclusion is not applicable, the clinician must submit a numerator of at least one to fulfill the measure.

After consideration of the public comments we received, we are finalizing the proposal to revise the description of the exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, as follows: Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period. We are also finalizing the proposal that the revised description of the exclusion will be applicable starting with the 2019 performance period/2021 MIPS payment year.

(iii) Public Health and Clinical Data Exchange—Syndromic Surveillance Reporting

In the CY 2018 Quality Payment Program final rule (82 FR 53674), we established the measure description for the Syndromic Surveillance Reporting measure as follows: ''The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.'' However, in the CY 2019 PFS final rule (83 FR 59798), we inadvertently stated that the measure description was as follows: ''The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from a *non*-urgent care setting'' (emphasis added). We did not intend to replace ''urgent care'' with ''non-urgent care'' in the measure description, and we regret any confusion our typographical error may have caused. To alleviate any future confusion surrounding the description, we are restating the measure description for the Syndromic Surveillance Reporting measure here and in the table below as follows: ''The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting''.

For ease of reference, Table 48 lists the objectives and measures for the Promoting Interoperability performance category for the 2020 performance period as revised to reflect the final policies established in this final rule. For more information on the 2015 Edition certification criteria required to meet the objectives and measures, we refer readers to Table 43 in the CY 2019 PFS final rule (83 FR 59817).

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Part II—Continued

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 409, 410, et al.

Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine; Final and Interim Final Rules

TABLE 48: Objectives and Measures for the Promoting Interoperability Performance Category in 2020

Objective	Measure	Numerator	Denominator	Exclusion
e-Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
e-Prescribing: Generate and transmit permissible prescriptions electronically.	Query of PDMP (bonus): For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Objective	Measure	Numerator	Denominator	Exclusion
new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.				
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.	Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online,	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	download, and transmit his or her health information; and 2.The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	technical specifications of the API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active	Syndromic Surveillance Reporting: The MIPS eligible clinician is in active engagement with a public health	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician 1.Is not in a category of health care providers from which ambulatory syndromic data is collected by their jurisdiction's syndromic surveillance system;

Objective	Measure	Numerator	Denominator	Exclusion
engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	agency to submit syndromic surveillance data from an urgent care setting.			OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3.operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from MIPS eligible clinicians as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where	Public Health Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not diagnose or directly treat any disease or condition associated with a public health registry in the MIPS eligible clinician's jurisdiction during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3.operates in a jurisdiction where no public health registry for which the

Objective	Measure	Numerator	Denominator	Exclusion
prohibited, and in accordance with applicable law and practice.				MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Clinical Data Registry Reporting: The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician 1. Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the performance period; OR 2.operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3.operates in a jurisdiction where no clinical data registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.

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(e) Scoring Methodology

(i) Changes to the Scoring Methodology for the 2020 Performance Period

In the CY 2019 PFS final rule (83 FR 59785 through 59796), we finalized a new performance-based scoring methodology for the Promoting Interoperability performance category beginning with the performance period in 2019. As previously discussed in section III.K.3.c.(4)(d)(i) of this final rule, we are finalizing our proposals for CY 2020 to: (1) Make the Query of PDMP measure optional and eligible for five bonus points in CY 2020; (2) make the e-Prescribing measure worth up to 10 points in CY 2020, and (3) remove the Verify Opioid Treatment Agreement measure beginning in CY 2020. Table 49 reflects the proposals that we are finalizing, although the maximum points available do not include points that would be redistributed in the event that an exclusion is claimed.

TABLE 49: Scoring Methodology for the Performance Period in 2020

Objectives	Measures	Maximum Points
e-Prescribing	e-Prescribing*	10 points
	Query of PDMP	5 points (*bonus*)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information*	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information*	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: Immunization Registry Reporting* Electronic Case Reporting* Public Health Registry Reporting* Clinical Data Registry Reporting* Syndromic Surveillance Reporting*	10 points

* Exclusion available.

(f) Additional Considerations

(i) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

In prior rulemaking (83 FR 59818 through 59819), we discussed our belief that certain types of MIPS eligible clinicians (NPs, PAs, CNSs, and CRNAs) may lack experience with the adoption and use of CEHRT. Because many of these non-physician clinicians were or are not eligible to participate in the Medicare or Medicaid EHR Incentive Program (now known as the Promoting Interoperability Program), we stated that we have little evidence as to whether there are sufficient measures applicable and available to these types of MIPS eligible clinicians under the advancing care information (now known as Promoting Interoperability) performance category. We established a policy at § 414.1380(c)(2)(i)(A)(5) for the performance periods in 2017, 2018, and 2019 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the Promoting Interoperability performance category, but if they choose to report, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act. We stated our intention to use data from the first performance period (2017) to further evaluate the participation of these MIPS eligible clinicians in the Promoting Interoperability performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians.

We have analyzed the data submitted for the 2017 performance period for the Promoting Interoperability performance category, and have discovered that the vast majority of MIPS eligible clinicians submitted data as part of a group. While we are pleased that MIPS eligible clinicians utilized the option to submit data as a group, it does limit our ability to analyze data at the individual NPI level. For example, when a group of MIPS eligible clinicians chooses to report for MIPS as a group, the data submitted are representative of that entire group, as opposed to each individual MIPS eligible clinician in the group submitting data that exclusively reflect his/her own performance. Approximately 4 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for MIPS, and more than two-thirds of them did not submit data for the Promoting Interoperability performance category. Additionally, we are challenged because many of the measures that were available for submission for the 2017 performance period are now unavailable, due to our discontinuation of the Promoting Interoperability transition measure set, and the overhaul of the performance category that further reduced the number of available measures. For these reasons, we were unable to determine, at the time we were developing the CY 2020 PFS proposed rule, whether the measures currently specified for the Promoting Interoperability performance category for the 2020 performance period are applicable and available for NPs, PAs, CRNAs, and CNSs. However, as more data become available, we plan to reevaluate the measures and consider how we could ensure that there are sufficient measures applicable and available for these types of MIPS eligible clinicians.

Therefore, we proposed to continue the existing policy of reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2020, and to revise § 414.1380(c)(2)(i)(A)(*5*) to reflect this proposal.

We received public comments on our proposals and the following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported our proposal to continue to reweight the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2020.

Response: We agree that reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for CY 2020 is appropriate. We hope that in the future more of these clinician types will be utilizing CEHRT and will be able to submit data for this performance category.

After consideration of the comments, we are finalizing our proposal to

continue the existing policy of reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2020, and to revise § 414.1380(c)(2)(i)(A)(*5*) to reflect this policy.

(ii) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologist, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2019 PFS final rule (83 FR 59819 through 59820), we adopted a policy at § 414.1380(c)(2)(i)(A)(4) to apply the same automatic reweighting policy we adopted for NPs, PAs, CNSs, and CRNAs for the performance periods in 2017 through 2019 to these new types of MIPS eligible clinicians (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the performance period in 2019. Because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Programs, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category.

For the reasons discussed in section III.K.3.c.(4)(f)(i) of the CY 2020 PFS proposed rule (84 FR 40776), for the performance period in 2020, we proposed to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals, and to revise § 414.1380(c)(2)(i)(A)(4) to reflect this proposal. We invited comments on this proposal.

We received public comments on our proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported CMS' reweighting of the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals.

Response: We appreciate the support for our proposal.

Comment: Several commenters expressed their concerns about there not being appropriate measures in place to accommodate the practices of NPPs.

Response: Currently, the data from physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals is too limited to support the addition of measures that are tailored to the specific practices of NPPs. However, we encourage stakeholders to submit their ideas and suggestions to us during our annual call for measures.

Comment: One commenter suggested adding chiropractic clinicians to the automatic reweighting of the Promoting Interoperability performance category that is currently available for physical therapists, occupational therapists, and qualified speech-language pathologists, until additional meaningful measures are available.

Response: We thank the commenter for the suggestion. However, chiropractors were eligible professionals under section 1848(o)(5)(C) of the Act, and thus were eligible to participate in the Medicare EHR Incentive Program, unlike the types of NPPs mentioned by the commenter. The same rationale for reweighting the Promoting Interoperability performance category does not apply to chiropractors.

After consideration of the comments, we are finalizing the proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals, and to revise § 414.1380(c)(2)(i)(A)(4) to reflect this policy.

(iii) Hospital-Based MIPS Eligible Clinicians in Groups

We define a hospital-based MIPS eligible clinician under § 414.1305 as a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of services identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital (POS 21), on campus outpatient hospital (POS 22), off campus outpatient hospital (POS 19), or emergency room (POS 23) setting, based on claims for the MIPS determination period (81 FR 77238 through 77240, 82 FR 53686 through 53687, 83 FR 59727 through 59730). We established under § 414.1380(c)(2)(i)(C)(6) that a MIPS eligible clinician who is a hospital-based MIPS eligible clinician as defined in § 414.1305 will be assigned a zero percent weight for the Promoting Interoperability performance category, and the points associated with the Promoting Interoperability performance category will be redistributed to another performance category or categories (81 FR 77238 through 77240, 82 FR 53684, 83 FR 59871). However, if a hospital-based MIPS eligible clinician chooses to report on the Promoting Interoperability performance category measures, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score. We stated that this policy includes MIPS eligible clinicians choosing to report as part of a group or part of a virtual group (82 FR 53687).

Under § 414.1310(e)(2)(ii), individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN (81 FR 77058). For groups reporting on the Promoting Interoperability performance category, we stated that group data should be aggregated for all MIPS eligible clinicians within the group (81 FR 77214 through 77216, 82 FR 53687). We stated that this includes those MIPS eligible clinicians who may qualify for a zero percent weighting of the Promoting Interoperability performance category due to circumstances such as a significant hardship or other type of exception, hospital-based or ASC-based status, or certain types of NPPs (82 FR 53687). We established at § 414.1380(c)(2)(iii) that for MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability performance category to be reweighted, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting (82 FR 53687, 83 FR 59871). We have heard from several stakeholders that our policy for groups that include hospital-based MIPS eligible clinicians sets a threshold that is too restrictive for a variety of reasons. Some stated that due to high turnover rates for hospital medicine groups, many such groups rely on locum tenens clinicians who may practice in multiple settings. They stated that if a hospital medicine group includes only one MIPS eligible clinician who does not meet the definition of a hospital-based MIPS eligible clinician, it could prevent the group from qualifying for reweighting because not all of the MIPS eligible clinicians in the group would be considered hospital-based. A few acknowledged that while hardship

exceptions are available for MIPS eligible clinicians who lack control over CEHRT because they use the hospital's CEHRT, it is an administrative burden to have to submit a hardship exception application, especially if the clinician has a locum tenens relationship.

In the CY 2020 PFS proposed rule (84 FR 40776 through 40777), we stated our belief that hospital medicine groups may face unique circumstances due to the nature of their practice area and the staffing practices described by stakeholders. Thus, we proposed to revise the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. We proposed that, beginning with the 2022 MIPS payment year, a hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period.

We stated that we believe that a threshold of more than 75 percent is appropriate because it is consistent with the thresholds for groups in the definitions of facility-based MIPS eligible clinician and non-patient facing MIPS eligible clinician under § 414.1305. We proposed to revise § 414.1380(c)(2)(iii) to specify that for the Promoting Interoperability performance category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the proposed revised definition of a hospital-based MIPS eligible clinician (or the definition of a non-patient facing MIPS eligible clinician in § 414.1305, as proposed in section III.K.3.c.(4)(f)(iv) of the proposed rule (84 FR 40777).

The following is a summary of the public comments we received and our responses.

Comment: Commenters appreciated our proposal to lower the percentage of MIPS eligible clinicians that need to be considered hospital-based for a group or virtual group to be considered hospital-based. Commenters stated that a threshold of 100 percent was very difficult to achieve and a threshold of more than 75 percent is much more achievable. Some commenters stated that a threshold of more than 75 percent is reasonable and aligns with the threshold that CMS uses in the facility-based measurement approach in the MIPS cost and quality performance categories. Others believed that the proposed change will increase flexibility for clinicians practicing in a hospital setting. Another commenter stated that the revised definition better reflects the realities of practice. One commenter appreciated the recognition that the previous definition of a hospital-based groups was confusing and difficult for clinicians to meet and thanked CMS for our responsiveness to stakeholder concerns. Several commenters stated that the ''all or nothing rule'' (requiring 100 percent of the MIPS eligible clinicians in the group or virtual group to qualify for reweighting) was unfair and penalizes hospital-based clinicians who work in multi-specialty groups.

Response: We appreciate the support for our proposal and agree that a threshold of more than 75 percent would account for the unique circumstances faced by hospital-based groups such as locum tenens arrangements and high turnover rates.

Comment: One commenter urged CMS to consider reweighting a group if more than 75 percent of the group qualifies for reweighting for any reason.

Response: We appreciate this suggestion, but we believe that hospital medicine groups may face unique circumstances due to the nature of their practice area that clinicians who practice in non-hospital settings would not experience, and thus we decline to adopt the commenter's suggestion.

After consideration of the public comments, we are finalizing the proposal to revise the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. We are finalizing the proposal that, beginning with the 2022 MIPS payment year, a hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period. We are also finalizing the proposal to revise § 414.1380(c)(2)(iii) to specify that for the Promoting Interoperability performance category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the definition of a hospital-based MIPS eligible clinician or a non-patient facing MIPS eligible clinician as defined in § 414.1305.

(iv) Non-Patient Facing MIPS Eligible Clinicians in Groups

We define a non-patient facing MIPS eligible clinician under § 414.1305 as an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician. We established under § 414.1380(c)(2)(i)(C)(5) that a MIPS eligible clinician who is a non-patient facing MIPS eligible clinician as defined in § 414.1305 will be assigned a zero percent weight for the Promoting Interoperability performance category, and the points associated with the Promoting Interoperability performance category will be redistributed to another performance category or categories (81 FR 77240 through 77243, 82 FR 53680–53682, 83 FR 59871). However, if a non-patient facing MIPS eligible clinician chooses to report on the Promoting Interoperability performance category measures, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score. We stated that this policy includes MIPS eligible clinicians choosing to report as part of a group or part of a virtual group (82 FR 53687).

As noted in the CY 2020 PFS proposed rule (84 FR 40777), in connection with our discussion of hospital-based MIPS eligible clinicians in groups, under § 414.1380(c)(2)(iii), for

MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability performance category to be reweighted, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting. We proposed (84 FR 40777) to revise § 414.1380(c)(2)(iii) to account for groups and virtual groups that meet the revised definition of a hospital-based MIPS eligible clinician under § 414.1305, which would only require the group or virtual group to meet a threshold of more than 75 percent instead of a threshold of all of the MIPS eligible clinicians in the group or virtual group. In an effort to more clearly and concisely capture our existing policy for non-patient facing MIPS eligible clinicians, we proposed to revise § 414.1380(c)(2)(iii) to also account for a group or virtual group that meets the definition of a non-patient facing MIPS eligible clinician under § 414.1305, such that the group or virtual group only has to meet a threshold of more than 75 percent.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported a definition of a non-patient facing group as one in which more than 75 percent of the group's members qualify as non-patient facing and eligible for Promoting Interoperability performance category reweighting. One commenter noted that the clarification is helpful for physician groups that have a small number of patient facing clinicians embedded in a much larger group of non-patient facing clinicians.

Response: We believe that our proposed revision to the regulation text would help to alleviate confusion surrounding our policy for groups and virtual groups that include non-patient facing MIPS eligible clinicians.

Comment: One commenter suggested that CMS should make it easier for groups to evaluate whether they may qualify as hospital-based or non-patient facing by enhancing the Quality Payment Program Participation Status Tool on the Quality Payment Program website to show eligibility and special statuses for TINs, in addition to NPIs.

Response: We appreciate this suggestion and have added the ability to check eligibility for all clinicians associated with a practice as a feature of our Quality Payment Program Participation Status Tool.

After consideration of the public comments that we received, we are finalizing our proposal to revise § 414.1380(c)(2)(iii) to also account for a group or virtual group that meets the definition of a non-patient facing MIPS eligible clinician under § 414.1305, such that the group or virtual group only has to meet a threshold of more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician.

(g) Future Direction of the Promoting Interoperability Performance Category

In the CY 2020 PFS proposed rule (84 FR 40777 through 40784), we included Requests for Information regarding several issues involving the Promoting Interoperability performance category. While we are not summarizing and responding to comments we received in this final rule, we thank the commenters for their responses and we may take them into account as we develop future policies for the Promoting Interoperability performance category.

(5) APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

As codified at § 414.1370(a), the APM scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified on the Participation List for the performance period of an APM Entity participating in a MIPS APM.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77246), the APM scoring standard is designed to reduce reporting burden for these clinicians by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and MIPS.

We established at § 414.1370(c) that the MIPS performance period under § 414.1320 applies for the APM scoring standard. We finalized under § 414.1370(f) that the MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity, and the MIPS payment adjustment is applied at the TIN/NPI level for each MIPS eligible clinician in the APM Entity group. Under § 414.1370(f)(2), if the APM Entity group is excluded from MIPS, all eligible clinicians within that APM Entity group are also excluded from MIPS.

As finalized at § 414.1370(h)(1) through (4), the performance category weights used to calculate the MIPS final score for an APM Entity group for the APM scoring standard performance period are: Quality at 50 percent; cost at 0 percent; improvement activities at 20 percent; and Promoting Interoperability at 30 percent.

(b) MIPS APM Criteria

We established at § 414.1370(b) that for an APM to be considered a MIPS APM, it must satisfy the following criteria: (1) APM Entities must participate in the APM under an agreement with CMS or by law or regulation; (2) the APM must require that APM Entities include at least one MIPS eligible clinician on a Participation List; (3) the APM must base payment on quality measures and cost/utilization; and (4) the APM must be neither a new APM for which the first performance period begins after the first day of the MIPS performance year nor an APM in the final year of operation for which the APM scoring standard is impracticable. In the CY 2019 PFS final rule (59820 through 59821), we clarified that we consider whether each distinct track of an APM meets the criteria to be a MIPS APM and that it is possible for an APM to have tracks that are MIPS APMs and tracks that are not MIPS APMs. We also clarified that we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM.

Based on the MIPS APM criteria, we expect that the following 10 APMs will satisfy the requirements to be MIPS APMs for the 2020 MIPS performance period:

- Comprehensive ESRD Care Model (all Tracks).
- Comprehensive Primary Care Plus Model (all Tracks).
- Next Generation ACO Model.
- Oncology Care Model (all Tracks).
- Medicare Shared Savings Program (all Tracks).
- Medicare ACO Track 1+ Model.
- Bundled Payments for Care Improvement Advanced.
- Maryland Total Cost of Care Model (Maryland Primary Care Program).
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).
- Independence At Home Model.

Final CMS determinations of MIPS APMs for the 2020 MIPS performance period will be announced via the Quality Payment Program website at *https://qpp.cms.gov/*. Further, we make these determinations based on the established MIPS APM criteria as specified in § 414.1370(b).

(c) Calculating MIPS APM Performance Category Scores

(i) Quality Performance Category

As noted, the APM scoring standard is designed to reduce reporting burden

for MIPS eligible clinicians participating in MIPS APMs by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and MIPS. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77246), due to operational constraints, we did not require MIPS eligible clinicians participating in MIPS APMs other than the Shared Savings Program and the Next Generation ACO Model to submit data on quality measures for purposes of MIPS for the 2017 MIPS performance period. As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53695), we designed a means of overcoming these operational constraints and required MIPS eligible clinicians participating in such MIPS APMs to submit data on APM quality measures for purposes of MIPS beginning with the 2018 MIPS performance period. We also finalized a policy to reweight the quality performance category to zero percent in cases where an APM has no measures available to score for the quality performance category for a MIPS performance period, such as where none of the APM's measures would be available for calculating a quality performance category score by the close of the MIPS submission period because measures were removed from the APM measure set due to changes in clinical practice guidelines. Although we anticipated different scenarios where quality would need to be reweighted, we did not anticipate at that time that the quality performance category would need to be reweighted regularly.

After several years of implementation of the APM scoring standard, we have found that for participants in certain MIPS APMs (as defined in § 414.1305), it often is not operationally possible to collect and score performance data on APM quality measures for purposes of MIPS because these APMs run on episodic or yearly timelines that do not always align with the MIPS performance periods and deadlines for data submission, scoring, and performance feedback. In addition, although we anticipated different scenarios where quality would need to be reweighted, we do not believe the quality performance category should be reweighted regularly.

To achieve the aims of the APM scoring standard, we believe it is necessary to consider new approaches to quality performance category scoring.

(A) Allowing MIPS Eligible Clinicians Participating in MIPS APMs To Report on MIPS Quality Measures

We proposed to allow MIPS eligible clinicians participating in MIPS APMs to report on MIPS quality measures in a manner similar to our established policy for the Promoting Interoperability performance category under the APM scoring standard for purposes of the MIPS quality performance category beginning with the 2020 MIPS performance period.

Similar to our approach for the Promoting Interoperability performance category, we would allow MIPS eligible clinicians in MIPS APMs to receive a score for the quality performance category either through individual or TIN-level reporting based on the generally applicable MIPS reporting and scoring rules for the quality performance category. Under such an approach, we would attribute one quality score to each MIPS eligible clinician in an APM Entity by looking at both individual and TIN-level data submitted for the eligible clinician and using the highest reported score, excepting scores reported by a virtual group. Thus, we would use the highest individual or TIN-level score attributable to each MIPS eligible clinician in an APM Entity in order to determine the APM Entity score based on the average of the highest scores for each MIPS eligible clinician in the APM Entity.

As with Promoting Interoperability performance category scoring, each MIPS eligible clinician in the APM Entity group would receive one score, weighted equally with that of the other MIPS eligible clinicians in the APM Entity group, and we would calculate one quality performance category score for the entire APM Entity group. If a MIPS eligible clinician has no quality performance category score—if the individual's TIN did not report and the individual did not report—that MIPS eligible clinician would contribute a score of zero to the aggregate APM Entity group score.

We would use scores reported by an individual MIPS eligible clinician or a TIN reporting as a group; we would not accept virtual group level reporting because a virtual group level score is too far removed from the eligible clinician's performance on quality measures for purposes of the APM scoring standard.

We requested comment on our proposal.

We received several public comments on our proposal to use the highest TIN or individual score attributable to each MIPS eligible clinician, excepting virtual group level reporting, for purposes of the MIPS quality performance category beginning with the 2020 MIPS performance period. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to allow for MIPS quality measure reporting to be used in calculating a MIPS APM Entity score.

Response: We appreciate the commenters' support. We agree that this new approach will provide the best opportunity to score many MIPS eligible clinicians on quality performance.

Comment: Some commenters supported our proposal to allow scoring at the individual or group level to be rolled up to the APM Entity level, thereby allowing individuals in multi-specialty APMs to focus and be scored on measures most applicable to their practices.

Response: We thank commenters for their support. We agree that this approach would provide value by allowing individuals to be scored based on measures that are the most clinically relevant.

Comment: Some commenters expressed concerns about the additional reporting burden required to report on quality to both MIPS and their respective APMs. Some suggested that CMS make MIPS reporting optional for each APM Entity and create a quality category score only in situations where the APM Entity has elected to report.

Response: We acknowledge this proposed change in policy may introduce additional burden for some MIPS APM participants. We anticipate, however, this effect being limited to instances where participants' TINs do not already report separately to MIPS. We believe any potential burden will be further mitigated by our proposal to allow APM Entity-level quality reporting for MIPS, as discussed in section III.J.3.c.(5)(i)(C) of this final rule.

We remind commenters that we are required by section 1848(q)(5)(E)(i)(I) of the Act, to calculate a MIPS quality performance category score for MIPS eligible clinicians. As such, we cannot make MIPS reporting a wholly voluntary activity through regulatory action. Further, under a scenario in which no MIPS quality reporting was performed under any of the means available, section 1848(q)(5)(B)(i) of the Act requires the assignment of the lowest possible quality score.

After consideration of the comments, we are finalizing the proposal as proposed to require MIPS quality reporting by MIPS eligible clinicians in

MIPS APMs at either the APM Entity, TIN, or individual level.

(B) APM Quality Reporting Credit

We proposed to apply a minimum score of 50 percent, or an ''APM Quality Reporting Credit,'' under the MIPS quality performance category for certain APM entities participating in MIPS APMs where the APM quality data cannot be used for MIPS purposes as outlined below. Several provisions of the statute address the possibility of considerable overlap between the requirements of MIPS and those of an APM. Most notably, section 1848(q)(1)(C)(ii) of the Act excludes QPs and partial QPs who do not elect to participate in MIPS from the definition of a MIPS eligible clinician. In addition, under section 1848(q)(5)(C)(ii) of the Act, a MIPS eligible clinician's participation in an APM (as defined in section 1833(z)(3)(C) of the Act) earns such MIPS eligible clinician a minimum score of one-half of the highest potential score for the improvement activities performance category.

In particular, we believe that section 1848(q)(5)(C)(ii) of the Act reflects an understanding that APM participation requires significant investment in improving clinical practice, which may be duplicative with the requirements under the improvement activities performance category. We believe that MIPS APMs require an equal or greater investment in quality, which, due to operational constraints, cannot always be reflected in a MIPS quality performance category score. Accordingly, we proposed to apply a similar approach to quality performance category scoring under the APM scoring standard. We proposed that APM Entity groups participating in certain MIPS APMs receive a minimum score of one-half of the highest potential score for the quality performance category, beginning with the 2020 MIPS performance period. To clarify, our proposal was intended to apply specifically to those MIPS APMs that do not utilize MIPS measures and data collection types.

To the extent possible, we would calculate the final score by adding to the credit any additional MIPS quality score received on behalf of the individual NPI or the TIN. For the purposes of final scoring this credit would be added to any MIPS quality measure scores we receive. All quality category scores would be capped at 100 percent. For example, if the additional MIPS quality score were 40 percent, that would be added to the 50 percent credit for a total of 90 percent; if the quality score were 70 percent, that would be added to the 50 percent credit and because the result is 120 percent, the cap would be applied for a final score of 100 percent.

We received public comments on our proposal to calculate the quality performance category score for APM Entity groups participating in MIPS APMs where APM quality data cannot be used for MIPS purposes, to add to the applicable APM Entity level quality performance score a 50 percent quality reporting credit, for a total score of up to 100 percent. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our policy to provide a 50 percent quality reporting credit for those APM Entity groups that are participating in MIPS APMs that are already required to report quality measures for purposes of their APM, but for which the reported quality data cannot be used for MIPS purposes, to mitigate the duplicative reporting now required for MIPS quality scoring.

Response: We thank commenters for their support of our proposal.

Comment: A few commenters supported the use of an APM quality reporting credit, but urged CMS to make the credit 100 percent of the quality performance category.

Response: We appreciate the support for our proposed policy, but we do not believe that providing a quality reporting credit of 100 percent for the quality performance category would satisfy the statutory requirements at section 1848(q)(5)(E)(i)(I) of the Act that we measure ''performance'' on quality measures under the quality performance category. Furthermore, we do not believe that simply participating in a MIPS APM is a sufficient demonstration of performance on quality measures to warrant a score of 100 percent; rather, we interpret the statutory requirement at section 1848(q)(5)(D) of the Act to mean that we are to assess performance on quality measures not only for the sake of generating a score, but for the purpose of measuring year over year improvement, and rewarding those efforts as well. Therefore, we proposed to use a 50 percent quality reporting credit in combination with an achievement score in calculating an APM Entity's quality performance category score for APM Entity groups participating in MIPS APMs where quality data cannot be used for MIPS purposes.

Comment: Some commenters recommended that CMS increase the quality reporting credit to the minimum number of points required to ensure APM Entities receive a neutral payment adjustment under the APM scoring standard.

Response: We considered several different approaches for setting the APM Quality Reporting Credit, including an approach where the credit would be equal to the minimum number of points needed in the quality performance category which, when added to the automatic credit applied for the improvement activities performance category, would guarantee MIPS APM participants a MIPS score equal to or greater than the performance threshold for a given Quality Payment Program performance year. Upon further consideration, we found that such an approach would give MIPS APM participants a competitive advantage within MIPS as the performance threshold increased, but would function more as a safety net against a downward MIPS adjustment than as a reward for quality measure reporting that they had already done.

We believe that the APM Quality Reporting Credit of one-half of the performance category score better reflects the intent of rewarding a specific performance activity, reporting, than an approach where the primary purpose is to guarantee a specific outcome within the MIPS program.

Comment: Some commenters disagreed with our proposal to assign an APM Quality Reporting Credit for certain MIPS APM participants, as it would have the effect of raising the performance threshold and making it more difficult for other MIPS eligible clinicians to receive a top score.

Response: While we do anticipate that this APM Quality Reporting Credit may have an effect on APM Entities' quality performance category scores, our data suggest that the totality of our APM scoring standard policies should produce APM Entity quality performance category scores that are roughly equal to, or perhaps slightly lower than they would have been under the APM scoring standard rules if we had been able to implement them as finalized. We believe that the proposed approach would reward MIPS APM participants for the quality reporting they undertake within their APMs, which we had intended to but cannot use for purposes of MIPS, without unduly advantaging them relative to the MIPS performance threshold. With this in mind, we do not anticipate any negative impacts on other MIPS eligible clinicians as a result of this policy.

We are finalizing the policy to assign an APM Quality Reporting Credit of one-half of the quality performance category score under the APM scoring standard for APM Entity groups participating in MIPS APMs where

quality data cannot be used for MIPS purposes.

(aa) Exceptions From APM Quality Reporting Credit

Under this policy, we would not apply the APM Quality Reporting Credit to the APM Entity group's quality performance score for those APM Entities reporting only through a MIPS quality reporting data submission types according to the requirements of their APM, such as the Medicare Shared Savings Program, which requires participating ACOs to report through the CMS Web Interface and the CAHPS for ACOs survey measures. In these cases, no burden of duplicative reporting would exist, and there would not be any additional unscored quality measures for which to give credit.

In the case where an APM Entity group is in an APM that requires reporting through a MIPS quality reporting data submission type under the terms of participation in the APM, should the APM Entity group fail to report on required quality measures, the individual eligible clinicians and TINs that make up that APM Entity group would still have the opportunity to report quality measures to MIPS for purposes of calculating a MIPS quality performance category score as finalized for all MIPS APMs in accordance with § 414.1370(g)(1)(ii). However, as in these cases no burden of duplicative reporting would exist, they would not receive the APM Quality Reporting credit.

We did not receive any comments on this proposal, and we are finalizing as proposed.

(C) Additional Reporting Option for APM Entities

We recognize that some APM Entities may have a particular interest in ensuring that MIPS eligible clinicians in the APM Entity group perform well in MIPS, or in reducing the overall burden of joining the APM Entity. Likewise, we recognize that some MIPS APMs, such as the CMS Web Interface reporters, already require reporting on MIPS quality measures as part of participation in the APM. Therefore, we proposed that, in instances where an APM Entity has reported quality measures to MIPS through a MIPS submission type and using MIPS data collection type on behalf of the APM Entity group, we would use that quality data to calculate an APM Entity group level score for the quality performance category. We believe this approach best ensures that all participants in an APM Entity group receive the same final MIPS score while reducing reporting burden to the greatest extent possible. We received no public comments on our proposal that in instances where an APM Entity reports quality measures to MIPS through a MIPS submission type and using MIPS data collection type on behalf of the APM Entity group, we will use that quality data to calculate an APM Entity group level score for the quality performance category. We are finalizing the policy as proposed.

(D) Bonus Points and Caps for the Quality Performance Category

In the 2018 Quality Payment Program final rule (82 FR 53568, 53700), we finalized our policies to include bonus points in the performance category score calculation when scoring quality at the APM Entity group level. Because these adjustments would, under the policies we are finalizing in section III.J.3.d.(1)(b) of this final rule, already be factored in when calculating an individual or TIN-level quality performance category score before the quality scores are rolled-up and averaged to create the APM Entity group level score, we proposed not to continue to calculate these adjustments at the APM Entity group level in the case where an APM Entity group's quality performance score is reported by its composite individuals or TINs. However, in the case of an APM Entity group that chooses to or is required by its APM to report on MIPS quality measures at the APM Entity group level, we proposed to continue to apply any bonuses or adjustments that are available to MIPS groups for the measures reported by the APM Entity and to calculate the applicability of these adjustments at the APM Entity group level.

The following is a summary of the comments we received and our responses.

Comment: A commenter supported this policy, as it eliminates possible duplicative awards of bonus points.

Response: We appreciate the commenter's support.

We are finalizing this policy as proposed.

(E) Special Circumstances

In prior rulemaking, with regard to the quality performance category, we did not include MIPS eligible clinicians who are subject to the APM scoring standard in the automatic extreme and uncontrollable circumstances policy or the application-based extreme and uncontrollable circumstances policy that we established for other MIPS eligible clinicians (82 FR 53780–53783, 53895–53900; 83 FR 59874–59875). However, in the CY 2020 PFS proposed rule (84 FR 40786), we proposed to allow MIPS eligible clinicians participating in MIPS APMs to report on MIPS quality measures and be scored for the MIPS quality performance category based on the generally applicable MIPS reporting and scoring rules for the quality performance category. We also had proposed that the same extreme and uncontrollable circumstances policies that apply to other MIPS eligible clinicians with regard to the quality performance category also should apply to MIPS eligible clinicians participating in MIPS APMs who would report on MIPS quality measures as proposed. Therefore, beginning with the 2020 MIPS performance period/2022 MIPS payment year and only with regard to the quality performance category, we proposed to apply the application-based extreme and uncontrollable circumstances policy (82 FR 53780–53783) and the automatic extreme and uncontrollable circumstances policy (83 FR 59874–59875) that we previously established for other MIPS eligible clinicians and codified at § 414.1380(c)(2)(i)(A)(6) and (8), respectively, to MIPS eligible clinicians participating in MIPS APMs who are subject to the APM scoring standard and would report on MIPS quality measures as proposed in section III.J.3.c.(5)(c)(i) of the CY 2020 PFS proposed rule. We also proposed to limit the application of these policies to the quality performance category because the policy we then proposed and now are finalizing pertains to reporting on MIPS quality measures.

Under the previously established policies, MIPS eligible clinicians who are subject to extreme and uncontrollable circumstances may receive a zero percent weighting for the quality performance category in the final score (82 FR 53780–53783, 83 FR 59874–59875). Similar to the policy for MIPS eligible clinicians who qualify for a zero percent weighting of the Promoting Interoperability performance category (82 FR 53701 through 53702), we proposed that if a MIPS eligible clinician who qualifies for a zero percent weighting of the quality performance category in the final score is part of a TIN reporting at the TIN level that includes one or more MIPS eligible clinicians who do not qualify for a zero percent weighting, we would not apply the zero percent weighting to the qualifying MIPS eligible clinician. The TIN would still report on behalf of the entire group, although the TIN would not need to report data for the qualifying MIPS eligible clinician. All MIPS eligible clinicians in the TIN who

are participants in the MIPS APM would count towards the TIN's weight when calculating the aggregated APM Entity score for the quality performance category.

However, in this circumstance, if the MIPS eligible clinician is a solo practitioner and qualified for a zero percent weighting, or if the MIPS eligible clinician's TIN did not report at the group level and the MIPS eligible clinician is individually eligible for a zero percent weighting, or if all MIPS eligible clinicians in a TIN qualified for the zero percent weighting, neither the TIN nor the individual would be required to report on the quality performance category and would be assigned a weight of zero when calculating the APM Entity's quality performance category score.

If quality performance data were reported by or on behalf of one or more TIN/NPIs in an APM Entity group, a quality performance category score would be calculated for, and would be applied to, all MIPS eligible clinicians in the APM Entity group. If all MIPS eligible clinicians in all TINs of an APM Entity group qualify for a zero percent weighting of the quality performance category, the quality performance category would be weighted at zero percent of the MIPS final score.

We solicited comments from the public in this discussion of how best to address the technical infeasibility of scoring quality for many of our MIPS APMs, and whether the above described policy or some other approach may be an appropriate path forward for the APM entity group scoring standard in CY 2020.

Comment: Several commenters supported the greater uniformity within MIPS through this policy.

Response: We appreciate the commenters' support.

After consideration of public comments, we are finalizing the policy as proposed.

(F) Request for Comment on APM Scoring Beyond 2020

We also solicited comments on potential policies to potentially be included in future years' rulemaking to further address the changing statutory incentives for APM participation in coming years. We want the design of the APM scoring standard to continue to encourage appropriate shifts of MIPS eligible clinicians into MIPS APMs and Advanced APMs while ensuring fair treatment for all MIPS eligible clinicians.

We noted in the CY 2020 PFS proposed rule (84 FR 40787) and reiterate now that the QP threshold will be increasing in future years, potentially resulting in larger proportions of Advanced APM participants being subject to MIPS under the APM scoring standard. At the same time the MIPS performance threshold will be increasing annually, gradually reducing the impact of the APM scoring standard on participants' ability to achieve a neutral or positive payment adjustment under MIPS.

We received public comments with general support for finding new ways to continue to reward APM participation without giving APM participants an undue advantage within MIPS, without specific support for or opposition to any potential approach discussed below. We continue to seek input form the stakeholder community as we continue to consider these and other policies that may be included in future rulemaking.

(aa) Sunsetting the APM Quality Reporting Credit for APM Entities

One approach we indicated we may consider beginning in the 2021 performance year would be to apply the APM Quality Reporting Credit described above, if finalized, to specific APM Entities for a maximum number of MIPS performance years; this may be set for all APMs or tied to the end of each APM's initial agreement period.

We discussed our belief that this approach would create an incentive for new APM Entity groups to continue to form and join new MIPS APMs while maintaining the incentive for APM Entity groups and MIPS eligible clinicians to continue to strive to achieve QP status.

(bb) Sunsetting the APM Quality Reporting Credit for Non-Advanced APMs

Similar to the first approach, we may consider an approach whereby we would implement the above approach to quality scoring and then phase out the APM Quality Reporting Credit for MIPS APMs that are not also Advanced APM.

We would have the option to implement this change by removing the APM Reporting Credit for non-Advanced MIPS APMs entirely at the end of a set number of years for all non-Advanced APMs (for example, 2 years).

Alternately, we could tie this sunsetting of the APM Quality Reporting Credit for a non-Advanced APM to the initial agreement period of each APM, creating a well-timed incentive for movement into APM tracks that are Advanced APMs after the initial agreement period after the start of the APM. This approach also would complement the shift we are seeing within APMs, such as the Shared Savings Program, to require APM participants to move into two-sided risk tracks and Advanced APMs within 2 to 5 years of joining the model or program.

(cc) Sunsetting the APM Quality Reporting Credit for APM Entities in One-Sided Risk Tracks

One possible way of acknowledging the uncertainty involved with joining an APM without extending the APM Reporting Credit to all APM participants would be to retain the APM Quality Reporting Credit for all two-sided risk APM tracks but to remove this credit for participants in all one-sided risk tracks except for those APM Entities in the first 2 years—or first agreement period—of a MIPS APM.

We believe this approach would help ease the transition from MIPS to APM participation and ultimately into Advanced APM participation. However, this approach would continue to provide the APM Quality Reporting Credit for participants in two-sided risk APMs who have not reached the QP threshold. In this way, we could create an incentive for APM participants to move towards Advanced APMs, even in situations where it is unlikely the participant would be able to reach the QP threshold.

(dd) Retain Different APM Quality Reporting Credits for Advanced APMs and MIPS APMs

Another available option would be to apply an APM Reporting Credit, as described above to all MIPS APM participants but base the available credit on the level of risk taken on in the MIPS APM. For example, the maximum 50 percent credit may continue to be available to APM Entities in MIPS APMs that are Advanced APMs while the value of the credit may be limited to 25 percent for participants in MIPS APMs that are one-sided risk tracks, or otherwise not Advanced APMs. We solicited comments on how we might best divide these tracks and address the advent of two-sided risk MIPS APMs that do not meet the nominal amount and financial risk standards in order to be considered an Advanced APM, and what an appropriate reporting credit would be for these tracks.

(ee) Other Options

We solicited comments and suggestions on other ways in which we could modify the APM scoring standard to continue to encourage MIPS eligible clinicians to join APMs, with an emphasis on encouraging movement toward participation in two-sided risk APMs that may qualify as Advanced APMs.

(d) Excluding Virtual Groups From APM Entity Group Scoring

Due to concerns that virtual groups could be used to calculate APM Entity group scores, we have excluded virtual group MIPS scores when calculating APM Entity group scores. Previously, we have effectuated this exclusion through the use and application of terms defined in § 414.1305, specifically, ''APM Entity,'' ''APM Entity group,'' ''group,'' and ''virtual group.'' To improve clarity around the exclusion of virtual group scores in calculating APM Entity group scores, we proposed to effectuate this exclusion more explicitly, by amending § 414.1370(e)(2) to state that the score calculated for an APM Entity group, and subsequently the APM Entity, for purposes of the APM scoring standard does not include MIPS scores for virtual groups.

We did not receive any comments on this proposal. We are finalizing this policy as proposed.

(e) MIPS APM Performance Feedback

As we discussed in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77270, and 82 FR 53704 through 53705, respectively), MIPS eligible clinicians who are scored under the APM scoring standard will receive performance feedback under section 1848(q)(12) of the Act.

Regarding access to performance feedback, while split-TIN APM Entities and their participants can only access their performance feedback at the APM Entity group or individual MIPS eligible clinician level, MIPS eligible clinicians participating in the Shared Savings Program, which is a full-TIN APM, were able to access their performance feedback at the ACO participant TIN level for the 2017 performance period. However, due to confusion caused by the policy in cases, where not all eligible clinicians in a Shared Savings Program participant TIN received the APM Entity score, for example eligible clinicians that terminate before the first snapshot, we intend to better align treatment of Shared Savings Program ACOs and their participant TINs with other APM Entities and, where appropriate, with other MIPS groups. We will continue to allow ACO participant TIN level access to the APM Entity group level final score and performance feedback, as well as provide the APM Entity group level final score and performance feedback to individual MIPS eligible clinicians who bill through the TINs identified on the ACO's ACO participant list. However, we will also provide TIN level performance feedback to ACO participant TINs that will include the information that is available to all TINs participating in MIPS, including the applicable final scores for MIPS eligible clinicians billing under the TIN, regardless of their MIPS APM participation status.

(f) Regulation Text

Due to a clerical error, the regulation text corresponding with the proposals discussed in section III.J.3.c.(5) of this final rule was omitted from the publication of the proposed rule. The proposals were discussed at length in the preamble where we solicited public comment. This preamble text included a detailed explanation of the proposed changes to the regulation text. The preamble text also cross-referenced the missing regulation text, such as page 84 FR 40786, such that the intent to codify the proposals would have been apparent to readers. We received several detailed public comments on our proposals. These comments indicate that readers accurately understood the proposed policy and our intent to codify it, and as discussed in section III.J.3.c.(5) of this final rule, were generally supportive of the proposal. As such, we are finalizing the proposed policies, as explained above, including amending § 414.1370(g)(1) accordingly.

d. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

For the 2022 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years, which allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. The rationale for our scoring methodology continues to be grounded in the understanding that the MIPS scoring system has many components and various moving parts. As we transform MIPS through the MVP framework as discussed in section III.K.3.a. of this final rule, we may propose modifications to our scoring methodology in future rulemaking as we continue to develop a methodology that emphasizes simplicity and that is understandable for MIPS eligible clinicians.

In the CY 2020 PFS proposed rule (84 FR 40788 through 40792), we proposed policies to help eligible clinicians as they participate in the 2020 performance period/2022 MIPS payment year, and as we move beyond the transition years of the program.

(b) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to § 414.1380(b)(1) for our policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category percent score, including achievement and improvement points, and the small practice bonus.

As we move towards the transformation of the program through the MVP Framework discussed in section III.K.3.a. of this final rule, we anticipate we will revisit and remove many of our scoring policies such as the 3-point floor, bonus points, and assigning points for measures that cannot be scored against a benchmark through future rulemaking. As we proposed to transform the MIPS program through the MVP framework, our goal was to incorporate ways to address these issues without developing special scoring policies. We refer readers to the 2020 PFS proposed rule (84 FR 40741 through 40742) for further discussion on scoring of MVPs.

In section III.K.3.d.(1) of this final rule, we discuss the limited proposals for our scoring policies as we anticipate future changes as we work to transform MIPS through the MVP framework. In the CY 2020 PFS proposed rule (84 FR 40788 through 40792), we proposed to: (1) Maintain the 3-point floor for measures that can be scored for performance; (2) develop benchmarks based on flat percentages in specific cases where we determine the measure's otherwise applicable benchmark could potentially incentivize inappropriate treatment; (3) continue the scoring policies for measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria; (4) maintain the cap on measure bonus points for high-priority measures and end-to-end reporting; and (5) continue the improvement scoring policy. In addition, we requested comment on future approaches to scoring the CAHPS for MIPS survey measure if new questions are added to the survey.

(i) Assigning Quality Measure Achievement Points

We refer readers to § 414.1380(b)(1) for more on our policies for scoring performance on quality measures.

(A) Scoring Measures Based on Achievement

We established at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable). MIPS eligible clinicians receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77282), we established that measures with a benchmark based on the performance period (rather than on the baseline period) would continue to receive between 3 and 10 measure achievement points for performance periods after the first transition year. For measures with benchmarks based on the baseline period, we stated that the 3-point floor was for the transition year and that we would revisit the 3-point floor in future years.

For the 2022 MIPS payment year, we proposed to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. As we move towards the MVP framework discussed in section III.K.3.a. of this final rule, we anticipate we will revisit and possibly remove the 3-point floor in future years. As a result, we will wait until there is further policy development under the MVP framework before proposing to remove the 3-point floor. Accordingly, we proposed to amend § 414.1380(b)(1)(i) to remove the years 2019, 2020, and 2021 and adding in its place the years 2019 through 2022 to provide that for the 2019 through 2022 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340. The number of measure achievement points received for each measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

We received public comments on our proposal to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS' proposal to maintain the 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period for the 2022 MIPS payment year because they believe the consistency makes it easier for clinicians to understand MIPS scoring complexities, improves workflow processes, offers a reasonable backstop for unpredictable performance, encourages program participation, and is critical for small and rural practices that have less resources and require more time to advance quality initiatives.

Response: We thank commenters for their support. As stated in the 2020 PFS proposed rule (84 FR 40788), as we move towards implementation of the MVP framework, we anticipate we will revisit the 3-point floor in future years since this scoring policy was intended to be temporary.

After consideration of the comments, we are finalizing our proposal for the MIPS 2022 payment year to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. We will amend § 414.1380(b)(1)(i) as proposed.

(B) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

We refer readers to § 414.1380(b)(1)(i)(A) and (B) for more on our scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement. A summary of the policies for the CY 2020 MIPS performance period is provided in Table 50.

TABLE 50: Quality Performance Category: Scoring Policies for the CY 2020 MIPS Performance Period*

Measure type	Description	Scoring rules
Class 1	For the 2020 MIPS performance period: Measures that can be scored based on performance. Measures that are submitted or calculated that meet all the following criteria: (1) Has a benchmark; (2) Has at least 20 cases; and (3) Meets the data completeness standard (generally 70 percent for 2020.)**	For the 2020 MIPS performance period: 3 to 10 points based on performance compared to the benchmark.
Class 2	For the 2020 MIPS performance period: Measures that are submitted and meet data completeness, but do not have either of the following: (1) A benchmark (2) At least 20 cases.	For the 2020 MIPS performance period: 3 points.
Class 3	For the 2020 MIPS performance period: Measures that are submitted, but do not meet data completeness threshold, even if they have a measure benchmark and/or meet the case minimum.	Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero measure achievement points. Small practices will continue to receive 3 points.

*The Class 2 and 3 measure scoring policies are not applicable to CMS Web Interface measures or administrative claims-based measures.

**We refer readers to section III.K.3.c.(1)(c) of this final rule for our policy to increase data completeness.

For the 2022 MIPS payment year, we proposed to again apply the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark or meet the case minimum requirement. Accordingly, we proposed to amend § 414.1380(b)(1)(i)(A)(*1*) to remove the years 2019, 2020, and 2021 and add in its place the years 2019 through 2022 to provide that except as provided in paragraph (b)(1)(i)(A)(2) (which relates to CMS Web Interface measures and administrative claims-based measures), for the 2019 through 2022 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

We received public comments on our proposal to again apply the special scoring policies for measures that meet the data completeness requirement, but do not have a benchmark or meet the case minimum requirement. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposal to retain the 3-point floor for small practices who submit data, but do not meet the data completeness threshold.

Response: We appreciate the commenter's support. However, we stress that these policies are not meant to be permanent, and as clinicians continue to gain experience with the program, we will revisit the appropriateness of these policies in future rulemaking.

Comment: A few commenters recommended incentivizing clinicians to report on new measures and measures without benchmarks by eliminating the scoring cap for measures with no benchmarks and providing clear and prospective benchmarks for new measures so that benchmarking data can be gathered and used since providers have little control over CMS-established benchmarks. A few commenters noted that low reporting rates are not an indication of low value or non-meaningful measures and as scoring is designed now, clinicians must choose between submitting data on a less relevant measure, with the potential to earn 10 points, or receiving the capped 3 points for submitting a relevant measure with no benchmark. A few commenters recommended that CMS include a bonus for submitting on new measures to incentivize the use and increase data collection.

Response: We recognize stakeholders' concerns regarding the assignment of 3 points to measures without a benchmark. We will take them into consideration in the future. As stated in the CY 2018 PFS final rule (82 FR 53729), we selected the 3-point cap because we did not want to provide more credit for reporting a measure that cannot be reliably scored against a benchmark than for measures for which we can measure performance against a benchmark. We remind commenters that we only apply the 3-point cap if we cannot create a benchmark for a measure. For many new measures, we do anticipate that a benchmark will be able to be created which will allow for up to 10 points. As we stated in the proposed rule (84 FR 40788), we envision that the progression of the MIPS program under the MVP framework will allow us to remove

some of the scoring complexity associated with the MIPS program. We anticipate that removing caps and bonuses could be part of this framework. As the program implementation continues, we want to ensure that our policies align with our goal of improving quality and decreasing burden. As such, we do not believe that eliminating or altering the finalized cap on the points available under the quality performance category for the 2022 MIPS payment year would support that goal.

After consideration of the comments, we are finalizing our proposal for the MIPS 2022 payment year to again apply the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark or meet the case minimum requirement. We will amend § 414.1380(b)(1)(i)(A)(*1*) as proposed.

(C) Modifying Benchmarks To Avoid the Potential for Inappropriate Treatment

We established at § 414.1380(b)(1)(ii) that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period. We also established at § 414.1380(b)(1)(i) that the number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution.

We believe all the measures in the MIPS program are of high standard as they have undergone extensive review prior to their inclusion in the program. MIPS measures go through the rulemaking process, and QCDR measures have an approval process before they are included in MIPS. We also believe our benchmarking generally provides an objective way to compare performance differences across different types of quality measures. However, we have heard concerns from stakeholders that for a few measures, the benchmark methodology may incentivize the inappropriate treatment of certain patients, in order for a clinician to achieve a score in the highest decile. Our scoring system already provides some protection from inappropriate treatment because all clinicians in the top 10 percent of the distribution receive the same 10-point score, thus a clinician with performance in the 90th percentile has no incentive to go higher. However, for certain measures with benchmarks set at very high or maximum performance in the top decile, we are concerned that these levels may not be representative and may not provide the most appropriate incentives for clinicians. Specifically, there are some measures that may have the potential to encourage clinicians to alter the clinical interaction with patients inappropriately, regardless of the individual patient's circumstances, in order to achieve that top decile performance level, for example, intermediate outcome measures that may encourage clinicians to over treat patients in order to achieve the highest performance level. Patient safety is our primary concern; therefore, we proposed to establish benchmarks based on flat percentages in specific cases where we determine the measure's otherwise applicable benchmark can potentially incentivize treatment that can be inappropriate for a particular patient type (84 FR 40789 through 40790). Rather than develop benchmarks based on the distribution of scores we will base them on flat percentages such that any performance rate at or above 90 percent will be in the top decile and any performance rate above 80 percent will be in the second highest decile, and this will continue for the remaining deciles. We believe the measures that will fall under this methodology are high-priority or outcome measures for clinicians to focus on. However, we want to ensure that benchmarks are set to incentivize the most appropriate behavior, and ensure that our method for scoring against a benchmark accurately reflects performance and does not result in clinicians receiving low scores, despite adherence to the most appropriate treatment.

For the measures identified, we proposed to use a flat percentage, similar to how the Shared Savings Program uses flat percentages to set benchmarks for measures with high performance. We selected this methodology for the following reasons: First, it is a straight-forward and simple methodology that currently exists for some MIPS measures that are collected through the CMS Web Interface. Second, because we are applying this methodology to measures with very high performance, we believe this approach is consistent with the Shared Saving Program approach established at § 425.502(b)(2)(ii) of using flat percentages to set benchmarks when many reporters demonstrate high achievement on a measure. The Shared Savings Program uses this method to avoid penalizing high ACO performance; however, in this case, we will be applying the flat percentages to ensure that the benchmark does not result in inappropriate and potentially harmful patient treatment. We believe this adjustment will provide additional protection to patients and reduce the potential incentive for inappropriate treatment of patients.

We proposed that to determine whether a measure benchmark may not provide the most appropriate incentives for treatment, thus creating the potential for inappropriate treatment based on the patient's circumstances, CMS medical officers will assess if there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure benchmark. This assessment will include reviews of factors such as whether the measure specifications allow for clinical judgment to adjust for inappropriate outcomes, if the benchmarks for any of the impacted measure's collection types could put these patients at risk by setting a potentially harmful standard for top decile performance, or whether the measure is topped out. The intent of the assessment is to have CMS medical officers determine whether certain measure benchmarks may have unintended consequences that put patients at risk and the measure benchmark should therefore move to a flat percentage. The assessment will take into account all available information, including from the medical literature, published practice guidelines, and feedback from clinicians, groups, specialty societies, and the measure steward. Before applying the flat percentage benchmarking methodology to any recommended measure, we will propose the modified benchmark for the applicable MIPS payment year through rulemaking. This policy will be effective beginning with the CY 2020 MIPS performance period (and thus the 2022 MIPS payment adjustment year). We also solicited comment on future actions we should take to help us in determining which measures to apply the flat percentage benchmarking to; for example, convening a technical expert panel.

We have identified two measures for which we believe we need to apply benchmarks based on flat percentages to avoid potential inappropriate treatment—MIPS #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control >9%) and MIPS #236 (NQF 0018): Controlling High Blood Pressure. Although there are protections built into both of these measures, such as the use of less stringent requirements than current clinical guidelines, they lack comprehensive denominator exclusions and risk-adjustment or risk-stratification, which can lead to the possible over treatment of patients in order to meet numerator compliance.

Overtreatment could lead to instances where the patient's blood sugar or blood pressure is lowered to a level that meets the measure standard but is too low for their optimum health given other coexisting medical conditions.

Because the factors for determining if a measure benchmark has the potential to cause inappropriate treatment may include both measure and benchmark considerations, we are concerned that all the benchmarks associated with the different collection types of a measure could be affected. Therefore, we proposed to use the flat percentage benchmarks as an alternative to our standard method of calculating benchmarks by a percentile distribution of measure performance rates under for all collection types where the top decile for any measure benchmark is higher than 90 percent under the performance-based benchmarking methodology at § 414.1380(b)(1)(ii) (84 FR 40790). We are limiting the application of the flat percentage methodology to all collection types where the top decile for any measure benchmark is higher than 90 percent so that our flat percentage methodology will actually reduce or remove the incentive for inappropriate care. If the top decile was originally below 90 percent, using the flat percentages would actually raise the level up to 90 percent, and therefore, provide a stronger incentive to provide inappropriate care in order to get the top score. We also solicited comment on whether we should use a criteria different than applying it to collection types where the top decile would be higher than 90 percent if the benchmark was based on a distribution. For the two measures we proposed to modify, we will not know which benchmarks and their associated collection types are impacted until we run our analysis; however, based on the benchmarks for the 2019 MIPS performance period, we anticipate using the modified benchmarks for the Medicare Part B claims and the MIPS CQM collection types.

We considered whether we should rerun the benchmarks excluding those in the top decile but are concerned that the approach will add complexity to the program overall. We solicited comment on whether we should consider different methodologies for the modified benchmarks such as excluding the top decile or increasing the required data completeness for the measure to a very high level (for example, 95 to 100 percent) and use performance period benchmarks rather than historical benchmarks.

We proposed to add paragraph § 414.1380(b)(1)(ii)(C) to state that beginning with the 2022 MIPS payment year, for each measure that has a benchmark that CMS determines has the potential to result in inappropriate treatment, we will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology at § 414.1380(b)(1)(ii). We also proposed to revise the text at § 414.1380(b)(1)(ii) to provide exceptions and to clarify the requirement that benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

We received public comments on our proposals to set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology if there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure, and our proposal to apply the flat percentages to the following two measures: MIPS #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9) and MIPS #236 (NQF #0018), Controlling High Blood Pressure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology if there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure. One commenter supported our proposal to apply the flat percentages to the following measure: MIPS #236 (NQF #0018), Controlling High Blood Pressure, to avoid inappropriate treatment. This commenter expressed concern that a one-size-fits-all blood pressure goal of < 140/90 mm Hg may erroneously suggest to patients and their clinicians that their treatment is adequate if they reach this goal. Another commenter supported our proposal to propose any specific measures to which they would apply this methodology through formal rulemaking to allow for stakeholder input.

Response: We appreciate the commenters' support. We believe identifying these measures through rulemaking provides a transparent process for the public to provide feedback.

Comment: One commenter suggested that CMS apply flat percentage benchmarks to otherwise ''topped out'' patient safety measures that should remain in the program due to their importance to patient safety.

Response: We intend to apply this policy to all measures with potential for inappropriate treatment based on the patient's circumstances. We believe it is important that we take a performance based approach to scoring, such that our benchmarks are based on a distribution of scores. We do not believe it would be appropriate to apply this standard broadly to a measure without this analysis. We recommend that stakeholders contact us through our service center if they have identified a measure that they believe would meet the requirements to apply flat percentage benchmarks so that we may consider it for future rulemaking. We may consider in future years revisiting flat percentage benchmarks as we transform MIPS through the implementation of the MVP framework discussed in section III.K.3.a. of this final rule. We also note that the measures that we selected to apply the flat percentage benchmarks to are not topped out for any of the collection types.

Comment: Several commenters recommended different methodologies that CMS could consider for the modified benchmarks. Several commenters encouraged CMS to use an approach where certain thresholds are determined based on expert opinion but interim values are informed by actual performance. Recognizing that this would be a more complex approach, these commenters believed that the thresholds should always be determined in part by data driven aspects such as peer performance and clinical evidence, in addition to manually fixed thresholds to ensure clinical relevance and fairness of measure benchmarks.

A few commenters encouraged CMS to use other methods of setting benchmarks, such as adding exclusions or risk stratifications to all measures, or reducing all benchmarks for all measures, including all collection types, by a certain percentage, an equivalent number of points. One commenter suggested that CMS consider developing benchmarks based on actual performance, with a cap based on rates for the highest performers and partial credit for achieving progress toward the target.

Response: We agree with commenters that using a data driven approach to benchmarks is preferred. While we received some information about the different methods, we do not believe we have sufficient information to conduct the analysis suggested for the measures we proposed to operationalize the alternatives for the 2020 MIPS

performance period. However, we are interested in working with stakeholders to better understand these alternative methods and would consider revising this policy through future rulemaking. Additionally, we plan to continue working with measure stewards to ensure the measures include appropriate exclusions or risk stratifications.

Comment: Several commenters did not support our proposal to set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology if there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure. While commenters recognized the need for a specialized approach, they expressed concerns regarding the consequences of this approach. Specifically, one commenter expressed concern that the measures proposed for the application of the flat percentages are claims based measures and MIPS CQMs, and that the application of the flat benchmark may unfairly lower the bar for clinicians utilizing the claims-based and MIPS CQM versions of the measures, without providing the same adjustment to all collection types. Another commenter expressed concern that the approach would lead to inconsistent evaluation of clinicians, as clinicians would be compared to their peers on some measures, but compared on flat thresholds on other measures that are unrelated to peer performance.

Response: We recognize that not applying the same benchmarking methodology to all collection types may create some inconsistent evaluation between collection types for a single measure. On the other hand, we know there are differences in performance by data collection type, and we are concerned that if we apply this method to all collection types without regard to the collection type distribution, then we would harm those with top performance for certain collection types. Given this tension, we believe it is better to limit the benchmark proposal to those collection types where the top decile is 90 percent or higher. We also intend to apply this policy in very limited circumstances where there is a concern with incentives for inappropriate treatment. At this time, we are proceeding cautiously with this approach by limiting application of this policy to two measures and two collections types. We may revisit this policy through future rulemaking.

Comment: A few commenters did not support our proposal to apply the flat percentages to the following measures: MIPS #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9) and MIPS #236 (NQF #0018), Controlling High Blood Pressure. These commenters expressed concern that the approach would not address the issue of potential inappropriate care, inappropriate treatment is rare for these measures, and our approach could potentially discourage appropriate care. A few commenters suggested that addressing exclusions for these measures might solve the issue of potential inappropriate care. However, another commenter cautioned against an approach based on exclusions. This commenter expressed concern that exclusions would not address every possible circumstance for each measure, and that expanding exclusions may have the inverse consequence of having systems focus on documentation improvements instead of clinical quality improvements.

Response: For these two measures, we have heard concern from stakeholders that clinicians may feel pressure to meet the measures standards at a high level, which could result in inappropriate treatments in patients for whom the specified level of control of blood pressure or blood sugar may be different from the precise measure specifications. As long as the percent of these patients (those who may be at risk because they fall in this category) is less than 10 percent of the practice's eligible cases, our flat benchmark approach can completely remove any potential incentive to over-treat. While this approach would allow the same score (10 points) for any clinician who chose to lower their performance down to 90 percent from a higher level, we believe that the clinicians for whom this would be possible are already high performing clinicians who would not knowingly undertreat their patients. Regarding commenters' concerns around exclusions, the measure steward for these two measures has advised CMS of additional denominator exclusions for the 2022 MIPS payment year and future years. We refer readers to Appendix 1, Table Group D (Previously Finalized Quality Measures with Substantive Changes Finalized for the 2022 MIPS Payment Year and Future Years) for additional details regarding these changes to the measures. We plan to continue working with measure stewards to ensure the measures include appropriate exclusions or risk stratifications. Additionally, we will work with stakeholders to better understand alternative methods and we may revisit this policy through future rulemaking.

Comment: One commenter recommended that when CMS determines a collection type for a measure where the top decile is higher than 90 percent under the methodology if there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure, then CMS should either remove the measure from that specific collection type or modify the measure so that inappropriate actions do not count positively, or remove and replace the measure.

Response: As noted in the CY 2020 Quality Payment Program proposed rule (84 FR 40751) and referred to in section III.K.3.c.(1)(d)(iv) of this final rule, we have established a robust set of removal criteria for quality measures. We will continue to work with quality measure stewards on future modifications of the measures and may consider removing or replacing any measures through notice and comment rulemaking as appropriate. At this time, we believe that the flat percentage benchmarks will allow the measure to stay in the program without incentivizing inappropriate care. We did not propose that we would substantively change the measures from their original state, as would be done if we were to no longer count patients that meet the requirements of the numerator when performance is high, as suggested by the commenter. However, we may consider this approach and consider removal of collection types through future rulemaking. We encourage stakeholders to develop meaningful measures that promote the quality outcomes and interactions for patients, additional viable quality measures, and robust performance data.

After consideration of public comments, we are finalizing a policy to use the flat percentage benchmarks as an alternative to our standard method of calculating benchmarks by a percentile distribution of measure performance rates for all collection types where the top decile for any measure benchmark is higher than 90 percent and when CMS medical officers assess that there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure benchmark. We will revise the text at § 414.1380(b)(1)(ii) as proposed and add paragraph § 414.1380(b)(1)(ii)(C) to state that beginning with the 2022 MIPS payment year, for each measure that has a benchmark that CMS determines has the potential to result in inappropriate treatment, we will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology at § 414.1380(b)(1)(ii). We are also finalizing our proposal to apply the flat percentages to the following two

measures: MIPS #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) and MIPS #236 (NQF #0018): Controlling High Blood Pressure.

(ii) Request for Feedback on Additional Policies for Scoring the CAHPS for MIPS Survey Measure

We refer readers to § 414.1380(b)(1)(vii)(B) for more on our policy on reducing the total available measure achievement points for the quality performance category by 10 points for groups that submit 5 or fewer quality measures and register for the CAHPS for MIPS survey, but do not meet the minimum beneficiary sampling requirements.

In the CY 2020 PFS proposed rule (84 FR 40791), we did not propose any changes to the scoring of the CAHPS for MIPS survey measure. However, to the extent consistent with our authority to collect such information under section 1848(q) of the Act, we considered expanding the information collected in the CAHPS for MIPS survey measure, described in section III.K.3.c.(1) of this final rule, and solicited comment on scoring. One consideration is adding narrative questions to the CAHPS for MIPS survey measure, which would invite patients to respond to a series of questions in free text, such as responding to open ended questions and describing their experience with care in their own words. We believe narratives from patients about their health care experiences would be helpful to other patients when selecting a clinician and can provide a valuable complement to standardized survey scores, both to help clinicians understand what they can do to improve care and to engage and inform patients about differences among their experiences of care. On the other hand, there may be concerns about the accuracy and usefulness of narrative information reported by patients. For more information on the rationale for adding narrative questions, we refer readers to the CY 2020 PFS proposed rule (84 FR 40746 through 40747). In addition, we are interested in learning from organizations with experience scoring narrative information, including methodologies. We will work with stakeholders on user testing before proposing any such methodology in future rulemaking. We also considered adding an additional CAHPS for MIPS survey question allowing patients to provide a score for their overall experience and satisfaction rating with a recent health care encounter, to capture the patient ''voice'' and provide patients with information useful to making a decision on clinicians, as detailed in the CY 2020 PFS proposed rule (84 FR 40744). We received feedback regarding how to score this measure and on new questions that could potentially be added to the calculation for a score for the CAHPS for MIPS survey measure. We will consider the feedback received for future notice and comment rulemaking.

(iii) Scoring for MIPS Eligible Clinicians That Do Not Meet Quality Performance Category Criteria

In the CY 2019 PFS final rule (83 FR 35950), we finalized our proposal to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen.

In the CY 2020 PFS proposed rule (84 FR 40791), we did not propose any changes to this policy. However, we refer readers to section III.K.3.d.(2)(b)(ii)(A) of this final rule for discussion on the rare circumstances when we are unable to calculate a quality performance category score for a MIPS eligible clinician because they do not have applicable or available quality measures. If we are unable to score the quality performance category for a MIPS eligible clinician, then we will reweigh the clinician's quality performance category score according to the reweighting policies described in sections III.K.3.d.(2)(b)(iii) of this final rule.

(iv) Incentives To Report High-Priority Measures

We refer readers to § 414.1380(b)(1)(v)(A) for more on the cap on high-priority measure bonus points for the first 3 years of MIPS at 10 percent of the denominator (total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category) of the quality performance category.

In the CY 2019 PFS final rule (83 FR 59851), we finalized technical updates to § 414.1380(b)(1) to more clearly and concisely capture previously established policies in the section. During this effort we inadvertently added that a high priority measure must have a benchmark. This was not intended to be a policy change. We are clarifying that in order for a measure to qualify for high priority bonus points it must meet case minimum and data completeness and not have a zero percent performance. The measure does not need to have a benchmark. Accordingly, we proposed to revise § 414.1380(b)(1)(v)(A)(*1*)(*i*) to provide that each high priority measure must meet the case minimum requirement at paragraph (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero (84 FR 40791).

We also removed high priority bonus points for CMS Web interface reporters in the CY 2019 PFS final rule (83 FR 59850 through 59851). We refer readers to the CY 2019 PFS final rule for further discussion on this policy.

In the CY 2020 PFS proposed rule (84 FR 40791), we proposed to maintain the cap on measure points for reporting high priority measures for the 2022 MIPS payment year. Accordingly, we proposed to revise § 414.1380(b)(1)(v)(A)(*1*)(*ii*) to remove the years 2019, 2020, and 2021 and adding in its place the years 2019 through 2022 to provide that for the 2019 through 2022 MIPS payment years, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

We received public comments on our proposal to clarify that a measure does not need to have a benchmark in order to qualify for high priority bonus points and our proposal to maintain the cap on measure points for reporting high priority measures for the 2022 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the high priority bonus and CMS' proposal to maintain the cap on measure points for reporting high priority measures for the 2022 MIPS payment year. One commenter cited an example cap at 10 percent of the total available measure achievement points through 2022 and expressed its belief that these points are helpful to the reporting of outcome and high priority measures and also that the consistency of scoring policy assists with provider understanding and approval of the program. A few commenters recommended that CMS continue to incentivize reporting by awarding MIPS bonus points or cross-category credit.

One commenter recommended further incentivizing bonus points for high priority measures because in some cases MIPS CQMs score higher than QCDR measures without the bonus points.

Response: We appreciate the recommendations. We agree that continuing the scoring policy provides consistency and will take the recommendations into consideration in the future rulemaking as we move toward the implementation of the MVP framework. We believe that our current policy of capping the high-priority measure bonus at 10 percent of the denominator prevents incentivizing the reporting of additional measures over a

focus on performance in relevant clinical areas, and mask poor performance with higher bonus points.

After consideration of the comments, we are finalizing our proposal to clarify that a measure does not need to have a benchmark in order to qualify for high priority bonus points and our proposal to maintain the cap on measure points for reporting high priority measures for the 2022 MIPS payment year. We will revise § 414.1380(b)(1)(v)(A)(*1*)(*i*) and (b)(1)(v)(A)(*1*)(*ii*) as proposed.

(v) Incentives To Use CEHRT To Support Quality Performance Category Submissions

We refer readers to § 414.1380(b)(1)(v)(B) for more on our policy assigning one bonus point for each quality measure submitted with end-to-end electronic reporting, under certain criteria.

In the CY 2020 PFS proposed rule (84 FR 40791), we proposed to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2022 MIPS payment year. We believe with the framework for transforming MIPS through the MVPs discussed in the 2020 PFS proposed rule (84 FR 40739), we can find ways in future years to incorporate eCQM measures without needing to incentivize end-to-end reporting with bonus points. As a result, we will wait until there is further policy development under the framework before proposing to remove our policy of assigning bonus points for end-to-end electronic reporting. Accordingly, we proposed to revise § 414.1380(b)(1)(v)(B)(*1*)(*i*) to remove the years 2019, 2020, and 2021 and add in its place the years 2019 through 2022 to provide that for the 2019 through 2022 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

We received public comments on our proposal to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2022 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to continue the end-to-end electronic reporting bonus points for providers utilizing electronic tools for MIPS reporting.

Response: We appreciate the commenters' support.

*Commen*t: A few commenters opposed the proposal to maintain the 10 percent cap on end-to-end electronic reporting points. Some commenters suggested that the MIPS scoring methodology should award credit across multiple MIPS performance categories and that continuing the cap on the bonus in the quality performance category would be counter to incentives to build capacity for digital data. A few commenters suggested that bonus points should be awarded in the PI performance category in addition to bonus points in the quality performance category.

Response: We appreciate commenters' concerns and will take their recommendations into consideration for the future. As we stated in the proposed rule (84 FR 40791), we envision that the progression of the MIPS program under the MVP framework will allow us to remove some of the scoring complexity associated with the MIPS program. We anticipate that removing bonuses would be part of this framework. As such, we do not believe that eliminating or altering the cap on the bonus points available under the quality performance category for the 2022 MIPS payment year would support that goal. We also understand the interest in being as flexible as possible in awarding clinicians for supporting the goals of the program such as reporting through end-to-end CEHRT. We will continue to consider the best ways to support this goal in future rulemaking.

After consideration of the comments, we are finalizing our proposal to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2022 MIPS payment year. We will revise § 414.1380(b)(1)(v)(B)(*1*)(*i*) as proposed.

(vi) Improvement Scoring for the MIPS Quality Performance Category Percent Score

We refer readers to § 414.1380(b)(1)(vi)(C)(*4*) for more on our policy stating that for the 2020 and 2021 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

In the CY 2020 PFS proposed rule (84 FR 40791 through 40792), we proposed to continue our previously established policy for the 2022 MIPS payment year and to revise § 414.1380(b)(1)(vi)(C)(*4*) to remove the phrase ''2020 and 2021 MIPS payment year'' and adding in its place the phrase ''2019 through 2022 MIPS payment years'' to provide that for the 2020 through 2022 MIPS payment years, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year. However, we misstated the replacement phrase, and clarify here that we will revise § 414.1380(b)(1)(vi)(C)(*4*) to remove the phrase ''2020 and 2021 MIPS payment year'' and add in its place the phrase ''2020 through 2022 MIPS payment years''. Specifically, for the 2022 MIPS payment year, we will compare the MIPS eligible clinician's quality performance category achievement percent score for the 2020 MIPS performance period to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent for the 2019 MIPS performance period.

The following is a summary of the comments we received and our responses.

Comment: One commenter supported CMS' proposal to assume the quality performance category achievement score equals 30 percent if MIPS eligible clinicians earned a quality performance category score less than or equal to 30 percent in the previous year.

Response: We thank the commenter for their support.

After consideration of the comments, we are finalizing our proposal to continue assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year. Consistent with our proposal, we will revise § 414.1380(b)(1)(vi)(C)(*4*) to remove the phrase ''2020 and 2021 MIPS payment year'' and add in its place the phrase ''2020 through 2022 MIPS payment years''.

(c) Facility-Based Measurement Scoring Option for the Quality and Cost Performance Categories for the 2022 MIPS Payment Year

(i) Background

For our previously established policies regarding the facility-based measurement scoring option, we refer readers to both the CY 2018 Quality Payment Program final rule (82 FR 53752 through 53767) and the CY 2019 PFS final rule (83 FR 59856 through 59867). In the CY 2019 PFS proposed rule (83 FR 35962 through 35963), we requested comments on a number of issues and topics related to whether we should expand the facility-based scoring option to other facilities and programs in future years, particularly the use of end-stage renal disease (ESRD) and post-

acute care (PAC) settings as the basis for facility-based measurement and scoring. We appreciate the many comments we received in response to this request. We did not propose an expansion to other facility types as part of this rule but may consider addressing this issue in future rulemaking.

(ii) Facility-Based Measurement Eligibility

In the CY 2019 PFS final rule (83 FR 59856 through 59860), we established the policies that determine eligibility for scoring for facility-based measurement as an individual and as a group. In the CY 2019 PFS final rule, we established at § 414.1380(e)(2)(i)(C) that a MIPS eligible clinician is facility-based if the clinician can be attributed, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period. While we did not propose any changes to the eligibility of facility-based measurement for individuals or groups, we proposed to amend § 414.1380(e)(2)(i)(C) to improve clarity (84 FR 40792). Specifically, we proposed to amend § 414.1380(e)(2)(i)(C) to state that a MIPS eligible clinician is facility-based if the clinician can be assigned, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period. We hope to avoid any ambiguity as we have used the term ''attribute'' and ''attribution'' in two ways. We have used the term to refer to the use of the facility's performance in place of the clinician's own performance (83 FR 59857). We have also used the term at § 414.1380(e)(2)(i)(C) to reference our method of connecting clinicians to a facility and indicate that the facility score will be the clinician's score. We believe these are related but distinct concepts; therefore, we proposed to revise § 414.1380(e)(2)(i)(C) to use the term ''assign'' instead of ''attribute.'' We believe this change in language more clearly describes how a clinician receives a score under facility-based measurement while avoiding making any changes to our methods in determining eligibility for facility-based measurement or their score. This does not constitute a change in policy.

We received public comments on our proposal to amend § 414.1380(e)(2)(i)(C) to state that a MIPS eligible clinician is facility-based if the clinician can be assigned, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our technical proposal which clarifies that a MIPS eligible clinician is facility-based if the clinician can be assigned to a facility, as opposed to saying attributed.

Response: We thank the commenter for their support.

After consideration of the public comments, we are finalizing our proposal to amend § 414.1380(e)(2)(i)(C) to state that a MIPS eligible clinician is facility-based if the clinician can be assigned, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period.

(iii) Facility-Based Measures for CY 2020 MIPS Performance Period/2022 MIPS Payment Year

For informational purposes, we are providing in Table 51 a list of the measures included in the FY 2021 Hospital VBP Program measure set that will be used in determining the quality and cost performance category scores for the CY 2020 MIPS performance period/ 2022 MIPS payment year. The FY 2021 Hospital VBP Program has adopted 12 measures covering 4 domains (83 FR 20412 through 20413). The performance period for measures in the Hospital VBP Program varies depending on the measure, and some measures include multi-year performance periods. These measures are determined through separate rulemaking; the applicable rulemaking is usually the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) rule. We are using these measures, benchmarks, and performance periods for the purposes of facility-based measurement in accordance with § 414.1380(e)(1). The measures for FY 2021 Hospital VBP Program were summarized in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 41454 through 41455).

TABLE 51: FY 2021 Hospital VBP Program Measures

Short Name	Domain/Measure Name	NQF #	Performance Period
Person and Community Engagement Domain			
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)	January 1, 2019-December 31, 2019
Clinical Outcomes Domain			
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization	0230	July 1, 2016-June 30, 2019
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization	0229	July 1, 2016-June 30, 2019
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468	September 1, 2017-June 30, 2019
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893	July 1, 2016-June 30, 2019
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550	April 1, 2016-March 31, 2019
Safety Domain			
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138	January 1, 2019-December 31, 2019
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139	January 1, 2019-December 31, 2019
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753	January 1, 2019-December 31, 2019
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716	January 1, 2019-December 31, 2019
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717	January 1, 2019-December 31, 2019
Efficiency and Cost Reduction Domain			
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158	January 1, 2019-December 31, 2019

(d) Scoring the Improvement Activities Performance Category

For our previously established policies regarding scoring the improvement activities performance category, we refer readers to § 414.1380(b)(3), the CY 2018 Quality Payment Program final rule (82 FR 53767 through 53769), and the CY 2019 PFS final rule (83 FR 59867 through 59868). We also refer readers to § 414.1355 and the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53662), and the CY 2019 PFS final rule (83 FR 59776 through 59785) for our previously established policies regarding the improvement activities performance category generally and section III.K.3.c.(3) of this final rule, where we discuss our final policies for the improvement activities performance category.

(e) Scoring the Promoting Interoperability Performance Category

We refer readers to section III.K.3.c.(4) of this final rule, where we discuss our final policies for the Promoting Interoperability performance category.

For our previously established policies regarding scoring the Promoting Interoperability‘ performance category, we refer readers to § 414.1380(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77216–77227), the CY 2018 Quality Payment Program final rule (82 FR 53663 through 53670), and the CY 2019 PFS final rule (83 FR 59785 through 59796). We also refer readers to § 414.1375 and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), the CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), and the CY 2019 PFS final rule (83 FR 59785 through 59820) for our previously established policies regarding the Promoting Interoperability (formerly the advancing care information) performance category generally.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to § 414.1380(c) and the discussion in the CY 2017 Quality Payment Program final rule (81 FR 77319 through 77329), CY 2018 Quality Payment Program final rule (82 FR

53769 through 53785), and CY 2019 PFS final rule (83 FR 59868 through 59878). In the CY 2020 PFS proposed rule (84 FR 40793 through 40800), we proposed to continue the complex patient bonus for the 2022 MIPS payment year and proposed performance category reweighting policies for the 2022, 2023, and 2024 MIPS payment years. These proposals are discussed in more detail in this section of the final rule.

(a) Complex Patient Bonus for the 2022 MIPS Payment Year

In the CY 2019 PFS final rule (83 FR 59869 through 59870), under the authority in section 1848(q)(1)(G) of the Act, we finalized at § 414.1380(c)(3) to maintain the complex patient bonus, which we previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776), of up to five points to be added to the final score for the 2021 MIPS payment year. The complex patient bonus was developed as a short-term solution to address the impact patient complexity may have on MIPS scoring that we would revisit on an annual basis while we continue to work with stakeholders on methods to account for patient risk factors. Our overall goal for the complex patient bonus was twofold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. For a detailed description of the complex patient bonus finalized for prior MIPS payment years, please refer to the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776) and CY 2019 PFS final rule (83 FR 59869 through 59870).

For the 2020 MIPS performance period/2022 MIPS payment year, we proposed (84 FR 40793) to continue the complex patient bonus as finalized for the 2019 MIPS performance period/2021 MIPS payment year and to revise § 414.1380(c)(3) to reflect this policy. In the CY 2020 PFS proposed rule (84 FR 40794), we noted that although we intended to maintain the complex patient bonus as a short-term solution, we did not believe we had sufficient information available to develop a long-term solution to account for patient risk factors in MIPS such that we would be able to include a different approach in the proposed rule. Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology for MIPS. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals' health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, enacted October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. ASPE completed its first report [116] in December 2016, which examined the effect of individuals' socioeconomic status on quality, resource use, and other measures under the Medicare program, and included analyses of the effects of Medicare's current value-based payment programs on providers serving socially at-risk beneficiaries and simulations of potential policy options to address these issues. In the CY 2020 PFS proposed rule (84 FR 40794), we noted the second ASPE report is expected in October 2019. At the time of publication of this final rule, the report has not been released. When the report becomes available, we intend to consider its recommendations for future rulemaking. At the time of publication of the CY 2020 PFS proposed rule, we did not believe additional data sources were available that would be feasible to use as the basis for a different approach to account for patient risk factors in MIPS. We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

In the CY 2020 PFS proposed rule (84 FR 40794), we considered whether the data still support the complex patient bonus at the final score level. We replicated analyses similar to the ones presented in Table 27 of the CY 2018 Quality Payment Program final rule (82 FR 53776). These analyses used the data submitted for the Quality Payment Program for the 2017 MIPS performance period and assessed eligibility and final scores based on the proposals we made for the 2020 MIPS performance period/2022 MIPS payment year using the methodology described in the Regulatory Impact Analysis in section VI. of the CY 2020 PFS proposed rule (84 FR 40898 through 40900).

Overall, the analysis of preliminary data referenced in the CY 2020 PFS proposed rule (84 FR 40793 through 40795) shows a consistent relationship between the dual eligible ratio quartiles and the average MIPS final scores only for individuals, where the average MIPS final score decreases as the quartile increases. We saw slight differences in the average HCC risk score and dual eligible ratio quartiles for groups, but virtually no difference for average HCC risk score for individuals. However, we had only 1 year of data and we noted more recent data may bring different results. In addition, at the time of publication of the proposed rule, we were awaiting a second report from ASPE in October 2019 that we expected would provide more direction for our approach to accounting for risk factors in MIPS. We were concerned that without the information from ASPE and without observing a clear trend that would require a change in our methodology, making any changes beyond our proposal to continue this policy would be premature.

We received public comments on our proposal to continue the complex patient bonus for one additional year. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to continue the complex patient bonus for the 2022 MIPS payment year. One commenter urged CMS to exercise caution in updating the complex patient bonus based on MIPS final scores from the 2017 MIPS performance period because these scores did not include cost measures and do not fully capture scoring variation based on clinical or social risk factors. The commenter also indicated that additional policy changes could impact MIPS final scores.

Response: We agree that scoring changes over the different MIPS payment years could impact MIPS final scores. We clarify that our analysis in the CY 2020 PFS proposed rule (84 FR 40793 through 40795) used data submitted for the 2017 performance period but estimated eligibility and final scores for the 2020 performance period by proxying a score using the methods described in the CY 2020 PFS proposed

[116] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs (2016). Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

rule (84 FR 40894 through 40901) to supplement the gap in data needed to estimate scores for the 2020 performance period. The additional data sources included the following cost measures: Total per capita cost measure performance based on the proposed revised measure using claims data from October 2016 through September 2017; and the proposed revised MSPB clinician measure and the 10 proposed episode-based measures based on claims data from January through December of 2017 (84 FR 40898). Therefore, the estimates did include the cost measures that would apply for the 2020 performance period. The methodology in the Regulatory Impact Analysis of the CY 2020 PFS proposed rule (84 FR 40894 through 40901) also included the complex patient bonus from the 2018 performance period (84 FR 40899); however, we did not include that bonus in the final score used for this analysis because we wanted to assess the difference in final scores prior to the application of the complex patient bonus. This is consistent with our original analysis when we proposed the complex patient bonus in the CY 2018 Quality Payment Program proposed rule (82 FR 30136).

We have updated this analysis with the most recent data in Table 52. Specifically, as described in section VII.F.10 of this final rule, we used data submitted for the 2018 MIPS performance period as an input to estimate the 2020 MIPS performance period final scores.

TABLE 52: MIPS Simulated Average Final Score * BY HCC and Dual Eligible Ratio Quartiles for Individuals with 6+ Measures and Groups**

	Individuals with 6+ Measures	Group
HCC Quartile		
Quartile 1 – Lowest Average HCC	74.21	76.10
Quartile 2	73.87	79.48
Quartile 3	74.24	77.83
Quartile 4 – Highest Average HCC	74.80	73.31
Dual Eligible Ratio		
Quartile 1- Low Proportion of Dual	74.99	76.64
Quartile 2	73.24	79.18
Quartile 3	74.43	76.86
Quartile 4 – Highest Proportion of Dual Status	73.61	74.35

* Estimated final score prior to the application of the complex patient bonus using the methodology described in section VII.F.10 of this final rule.

** We restricted our analysis to individuals who reported 6 or more measures because we wanted to look at differences in performance for those who reported the 6 measures which are generally required under MIPS if there are six measures that apply to the MIPS eligible clinician, rather than differences in scores due to MIPS eligible clinicians not fully reporting for MIPS.

The updated analysis reinforces findings from the analysis in the CY 2020 PFS proposed rule (84 FR 40795), again failing to find a consistent linear relationship between HCC quartiles and MIPS final scores, or dual eligible ratio quartiles and MIPS final scores. In the earlier analysis a consistent linear relationship was still found for MIPS final scores for individual reporters and dual eligible ratio quartiles. In the updated analysis, we did not observe a consistent linear relationship for any reporting type or complexity measure. For example, for groups, we estimate mean MIPS final scores to be higher for groups in the second quartile of dual eligible ratio or HCC quartile, than for groups in the first, lowest quartile. For individuals, mean MIPS final scores are estimated to be slightly higher for those with the highest average HCC, than for those with the lowest average HCC. It appears that other, unmeasured factors in addition to HCC and dual eligible ratio may be impacting MIPS scores in the 2018 data. We do see differences from the top and bottom quartile in three of the four comparisons (individual-dual eligible quartiles, and in both group reporting comparisons), so we are intending to finalize as proposed. However, given the inconsistent findings, we intend to revisit the size and structure of the complex patient bonus through future rulemaking.

Comment: A few commenters pointed out perceived limitations in the use of the HCC risk score in calculating the complex patient bonus; specifically, they believed it does not fully capture factors that increase risk or complexity for many specialties. One commenter suggested that CMS identify new data sets and strategies to better represent clinical and social complexity. One commenter suggested that CMS use geographic location as a proxy for social risk because geographic location is often associated with available resources and access to medical care.

Response: We thank the commenters for their suggestions and will take them into consideration as we consider options for updating the complex patient bonus in future years. We hope to be able to reference the ASPE report findings in future rulemaking. The complex patient bonus was intended to be a temporary solution while more permanent solutions were identified. We understand that both HCC risk scores and dual eligibility have some limitations as proxies for social risk factors. However, we are not aware of data sources for indicators such as income and education that are readily available for all Medicare beneficiaries that would be more complete indices of a patient's complexity. Therefore, we have decided to pair the HCC risk score

with the proportion of dual eligible patients to create a more complete complex patient indicator than can be captured using HCC risk scores alone. We will evaluate additional options in future years based on any updated data or additional information to better account for social risk factors while minimizing unintended consequences and consider these as we move forward.

After consideration of public comments, we are finalizing our proposal for the 2020 MIPS performance period/2022 MIPS payment year, to continue the complex patient bonus as finalized for the 2019 MIPS performance period/2021 MIPS payment year, as well as our proposed revisions to § 414.1380(c)(3).

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77320 through 77329 and 82 FR 53779 through 53785, respectively), as well as the CY 2019 PFS final rule (83 FR 59870 through 59878). As finalized in section III.K.3.c.(2)(a) of this final rule, the cost performance category will make up 15 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year. As finalized in section III.K.3.c.(1)(b) of this final rule, the quality performance category will thus make up 45 percent of a MIPS eligible clinician's final score the 2022 MIPS payment year. As described in sections III.K.3.c.(2)(a) and III.K.3.c.(1)(b) of this final rule, we are not finalizing weights for the cost and quality performance categories for the 2023 and 2024 MIPS payment years. Table 53 summarizes the finalized weights for each performance category.

TABLE 53—WEIGHTS BY MIPS PERFORMANCE CATEGORY FOR THE 2022 MIPS PAYMENT YEAR

Performance category	2022 MIPS payment year (percent)
Quality	45
Cost	15
Improvement Activities	15
Promoting Interoperability	25

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity for each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician generally would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Under certain circumstances, however, a MIPS eligible clinician who fails to report could be eligible for an assigned scoring weight of zero percent and a redistribution of the performance category weights. For a description of our existing policies for reweighting performance categories, please refer to § 414.1380(c)(2) and the CY 2019 PFS final rule (83 FR 59871 through 59876).

(A) Reweighting Performance Categories Due to Data That Are Inaccurate, Unusable, or Otherwise Compromised

In the proposed rule (84 FR 40796 through 40797), we discussed our belief that measures and activities may not be available to a MIPS eligible clinician for the quality, cost, and improvement activities performance categories under section 1848(q)(5)(F) of the Act when data related to the measures and activities are inaccurate, unusable or otherwise compromised due to circumstances that are outside of the control of the MIPS eligible clinician or its agents. In addition, we discussed our belief that data that are inaccurate, unusable or otherwise compromised due to circumstances that are outside of the control of the MIPS eligible clinician or its agents could constitute a significant hardship for purposes of the Promoting Interoperability performance category under section 1848(o)(2)(D) of the Act. We proposed a new policy to allow reweighing for any performance category if, based on information we learn prior to the beginning of a MIPS payment year, we determine data for that performance category are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the MIPS eligible clinician or its agents. For more information on our reasons for this proposal, please refer to the proposed rule (84 FR 40796 through 40797).

For purposes of this reweighting policy, we proposed that reweighting would take into account both what control the clinician had directly over the circumstances and what control the clinician had indirectly through its agents. We intended the term agent to include any individual or entity, including a third party intermediary as described in § 414.1400, acting on behalf of or under the instruction of the MIPS eligible clinician. We solicited comments on this approach and possible alternatives for balancing efforts to allow reweighting in circumstances in which clinicians are not culpable for compromised data while maintaining financial incentives for clinicians, third party intermediaries and other parties to prevent and correct compromised data.

We proposed that our determination of whether reweighting will be applied under this policy could take into account any information known to the agency and we would consider the information we obtain on a case-by-case basis for reweighting. We anticipated considering information provided to us through routine communication channels for the Quality Payment Program by any submitter type as defined under § 414.1305, as well as other relevant information sources of which we are aware. We requested that third party intermediaries, to the extent feasible, inform MIPS eligible clinicians if the third party intermediary believes their data may have been compromised. To the extent third party intermediaries believe that MIPS data may be compromised, we encouraged them to provide us with a list of or other identifying information for all MIPS eligible clinicians who may have been affected by such issues, so that we may evaluate the circumstances in a timely

manner. We also encouraged MIPS eligible clinicians to contact us and self-identify if they believe they have compromised data; they should not rely solely on a third party intermediary to do so. We recognized that there may be scenarios when a MIPS eligible clinician or one or more of its agents becomes aware of potential data issues prior to submission of data. We solicited comment on whether and how our proposed reweighting policy should apply to these circumstances. We noted that compromised data are not true, accurate or complete for purposes of § 414.1390(b) or § 414.1400(a)(5) and knowing submission of compromised data may result in remedial action against the submitter. We noted that a MIPS eligible clinician should not submit data and should not allow the submission of his or her data if the MIPS eligible clinician knows that the data are inaccurate, unusable, or otherwise compromised.

We proposed to determine whether the requirements for reweighting are met by assessing if: (1) The MIPS eligible clinician's data are inaccurate, unusable, or otherwise compromised; and (2) the data are compromised due to circumstances outside of the control of the MIPS eligible clinician or agent. We would make the determination of whether the clinician's data are inaccurate, unusable or otherwise compromised based on documentation of the issue and its demonstrated effect on data of the particular MIPS eligible clinician. As noted above, we proposed to limit this policy to cases where data are compromised outside the control of the clinician or its agent because we do not want to create incentives for clinicians or third party intermediaries to knowingly submit compromised data and want to encourage clinicians and their agents to take reasonable efforts to correct data that they believe maybe not compromised. Factors relevant to whether the circumstances were outside the control of the clinician and its agents include: whether the affected MIPS eligible clinician or its agents knew or had reason to know of the issue; whether the affected MIPS eligible clinician or its agents attempted to correct the issue; and whether the issue caused the data submitted to be inaccurate or unusable for MIPS purposes. We solicited feedback on these factors and whether there are additional factors we should consider to determine if there should be reweighing based on compromised data. If we determine that a MIPS eligible clinician's data were compromised and the conditions for reweighting are met, we proposed to notify the clinician of this determination through the performance feedback that we provide under section 1848(q)(12) of the Act if feasible, or through routine communication channels for the Quality Payment Program. We emphasized that the proposed reweighting policy is solely intended to mitigate the potential adverse financial impact of compromised data on the MIPS eligible clinician; a determination under this policy that data are compromised due to circumstances outside of the control of the MIPS eligible clinician and its agent, and therefore, that reweighting will occur for that clinician does not indicate and should not be interpreted to suggest that a third party intermediary or other individual or entity could not be held liable for the compromised data.

We proposed to apply reweighting only in cases when we learn of the compromised data before the beginning of the associated MIPS payment year because we want to encourage MIPS eligible clinicians and their agents to inform us of these concerns in a timely basis so we can update our data sets timely, while minimizing the impacts to other stakeholders who utilize MIPS data. For example, the Physician Compare website utilizes MIPS data to provide information to patients, consumers and other stakeholders when selecting a clinician or group. We noted our concern that without the appropriate incentive to notify us in a timely manner, clinicians and their agents may delay disclosures that data may be compromised and with these delays the MIPS data could be in an increased state of flux which will reduce the usefulness of the data to stakeholders. We were interested in feedback on whether there are other factors we should consider when adopting a timeline for reweighting due to compromised data and whether the period should be broader. We solicited comment on whether we should restrict our reweighting due to compromised data to instances when we learn the relevant information prior to the beginning of the MIPS payment year and whether there are other incentives for MIPS eligible clinicians to alert us to concerns about compromised data. We emphasized that if we determine a MIPS eligible clinician has submitted compromised data for a performance category during the associated payment year or at a later point, the MIPS eligible clinician would not qualify for reweighting under this proposal. Instead, for the performance categories with compromised data, the clinician's performance category score would be zero and the scoring weight for the category would not be redistributed.

In summary, under the authority in sections 1848(q)(5)(F) and 1848(o)(2)(D) of the Act, we proposed at § 414.1380(c)(2)(i)(A)*(9),* and (c)(2)(i)(C)*(10),* beginning with the 2018 MIPS performance period and 2020 MIPS payment year, to reweight the performance categories for a MIPS eligible clinician who we determine has data for a performance category that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents if we learn the relevant information prior to the beginning of the associated MIPS payment year. In addition, we proposed to amend § 414.1380(c)(2)(i)(C) to ensure that the reweighting proposed at § 414.1380(c)(2)(i)(C)*(10),* would not be voided by the submission of data for the Promoting Interoperability performance category as is the case with other significant hardship exceptions. We solicited comment on this proposal and alternatives to potentially mitigate the impact on MIPS eligible clinicians who through no fault of their own have data in a performance category that are inaccurate, unusable or are otherwise compromised.

We received public comments on our proposal and alternatives to potentially mitigate the impact on MIPS eligible clinicians who through no fault of their own have data in a performance category that are inaccurate, unusable or are otherwise compromised. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to reweight MIPS eligible clinicians impacted by data that are inaccurate, unusable, or otherwise compromised. Commenters indicated that in instances when data are inaccurate, unusable, or otherwise compromised outside of the control of the MIPS eligible clinician, relief for the clinician is appropriate.

Response: We appreciate the commenters' support of our proposal.

Comment: One commenter supported our policy to apply reweighting beginning with the 2018 MIPS performance period and the 2020 MIPS payment year so that MIPS eligible clinicians impacted by circumstances during that year can be provided with relief.

Response: We appreciate the commenter's support. We believe it is important to apply this policy beginning with the 2018 performance period/2020 MIPS payment year in case any circumstances have occurred that impact this payment year that have been

recently discovered. MIPS eligible clinicians and third party intermediaries can alert CMS through the help desk at *QPP@cms.hhs.gov* regarding any data that they believe may be inaccurate, unusable or otherwise compromised.

Comment: One commenter supported our proposal that submission of data for the Promoting Interoperability performance category would not nullify reweighting under the proposed policy.

Response: We appreciate the commenter's support.

Comment: One commenter supported the proposal because the commenter believed it would promote competition among EHR vendors by removing a significant obstacle to switching vendors during performance periods.

Response: We thank the commenter for their support. However, we note that our goal for this proposal was to mitigate for MIPS eligible clinicians the potential adverse scoring impact of data that are inaccurate, unusable, or otherwise compromised, and we did not intend for the proposal to impact competition among vendors.

Comment: A few commenters provided suggestions for the types of circumstances where they believe actions by their third party intermediary could lead to data being inaccurate, unusable, or otherwise compromised outside of the control of the clinician or its agents. These include instances when the third party intermediary goes out of business, makes a data submission error, or experiences a loss of data (examples may include storage malfunction; or the vendor not capturing data appropriately, resulting in incorrect measure data).

Response: We believe that, depending on the specific circumstances and timing, these circumstances could be covered under this policy. We encourage MIPS eligible clinicians and their agents experiencing these types of circumstances to communicate with us as early as possible to provide details about the circumstances surrounding these events. We also note that, depending on the specific circumstances, we may determine that the conduct of the third party intermediary warrants taking remedial action or terminating the third party intermediary in accordance with § 414.1400(f).

Comment: One commenter expressed the belief that we should include circumstances under this policy where a third party intermediary experiences a cyberattack causing any of the following: loss of data, loss of access to data, inability to analyze data, inability to package data, inability to transmit data to CMS, or any other significant obstacle to data collection or submission. The commenter also suggested this policy should include circumstances when a third party intermediary experiences an extreme and uncontrollable event, such as a natural disaster.

Response: We believe that our policy could apply in cases when a MIPS eligible clinician or their agent is impacted by a cyberattack that causes the eligible clinician's data to be inaccurate, unusable, or otherwise unusable. We clarify that this could apply even in cases where data are not able to be submitted as a result of the attack. We note that eligibility for reweighting would depend on the specific circumstances and timing, including the safeguards that were in place to prevent such attacks. We further emphasize that there is an expectation that third party intermediary take reasonable steps to prevent these attacks from occurring, and that, depending on the circumstances, CMS may determine that the conduct of the third party intermediary warrants taking remedial action or terminating the third party intermediary in accordance with § 414.1400(f). Finally, we agree with the commenter that our policy could apply in cases when a third intermediary experiences a natural disaster that causes the MIPS eligible clinician's data to be inaccurate, unusable, or otherwise unusable.

Comment: One commenter urged us to consider applying the proposed policy to scenarios where hospital-based clinicians are impacted by changes in hospital contracts that occur midway through the year. One example provided was when a hospital contract with a group ends, and the group may only have incomplete data from that hospital and may not be able to fully or accurately report. Another example provided was where a group begins a new contract with a hospital late in the year and may not be able to receive enough data from the new or prior hospital to fully and accurately report for MIPS.

Response: We believe that our policy could apply in cases where a clinician's data are rendered inaccurate, unusable, or otherwise compromised due to changes in hospital contracts that are outside the control of the clinician or its agents; however, in the examples provided it is not clear that the data issues associated with the contract changes would meet these criteria. In cases where MIPS eligible clinicians undergo transitions in hospital contracts, we encourage MIPS eligible clinicians to work with their contracting hospital to obtain data, including in cases where the MIPS eligible clinician may terminate a contract or may initiate a new contract.

Comment: One commenter suggested that we ensure that the requirements for MIPS eligible clinicians to alert us of relevant information are not unduly burdensome. For instance, the commenter proposed that each MIPS eligible clinician associated with a single third party intermediary that has compromised its users' data should not be required to submit evidence to CMS that their data were impacted.

Response: We intend for our reweighting determinations to take into account information that we learn of from a variety of channels, including through various communication channels and through third party intermediaries. To the extent possible, when we learn of data that have been compromised and receive sufficient information to determine the conditions for reweighting have been met for a MIPS eligible clinician, we intend to provide reweighting without requiring any action on the part of the MIPS eligible clinician. However, there may be some circumstances under which we will be unable to reach a conclusion regarding reweighting unless the MIPS eligible clinician provides us with information. For example, if we become aware that a third party intermediary has a data integrity issue that has resulted in compromised data for some but not all of its customers, MIPS eligible clinicians could help us reach a determination regarding potential reweighting by providing us with information, such as their clinician identifiers (for example, TIN/NPI or other identifiers) and submission type, through the Quality Payment Program help desk.

Comment: A few commenters urged us to notify MIPS eligible clinicians as early as possible if the agency receives reports suggesting they may have compromised data and provide them with information to understand how they can correct the problem going forward. Commenters also suggested that we work with impacted MIPS eligible clinicians to identify alternative reporting options, if feasible.

Response: When we learn of circumstances that suggest MIPS data are inaccurate, unusable or otherwise compromised, we will aim to provide information to the MIPS eligible clinicians whose data may have been compromised on an ongoing and timely basis. In cases where the data concern is associated with a third party intermediary and the issue is identified prior to the data submission deadline,

we agree that it would be ideal for MIPS eligible clinicians to identify alternate arrangements if any that may allow them to submit uncompromised data. For example, in scenarios where the underlying source data are uncompromised a MIPS eligible clinician may be able to identify a new third party intermediary that may be able to utilize their source data.

Comment: One commenter indicated that we should not apply reweighting in cases when a MIPS eligible clinician knowingly submitted data that are inaccurate, unusable, or otherwise compromised.

Response: A MIPS eligible clinician who has submitted compromised data would receive a score of zero for the performance category. Eligible clinicians who unknowingly submitted compromised data, or were not able to submit data due to their data being compromised may be able to receive reweighting if the circumstances were outside their control. However, an eligible clinician who knowingly submits compromised data would not be eligible for reweighing because the submission of compromised data was within the clinician's control. In addition, we note that compromised data are not true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5), and knowing submission of compromised data may result in remedial action against the submitter.

Comment: One commenter requested clarification as to how we would determine what constitutes compromised data and whether the circumstances were outside the control of the MIPS eligible clinician.

Response: We appreciate the request for clarification. We intend to make this determination on a case-by-case basis based on information known to the agency.

Comment: One commenter suggested that we stipulate that we will not hold third party intermediaries who inform CMS of relevant circumstances liable under current fraud, waste, and abuse laws and regulations or current laws and regulations governing the certification of their products. The commenter pointed to policies elsewhere in HHS under which parties can limit their liability by self-disclosing prior misconduct as a potential guide for policy in MIPS. The commenter suggested a framework under which a health IT developer or third-party intermediary would not face liability in connection with compromised data if it discloses the issue to CMS and eligible clinicians in good faith.

Response: We intended for this policy to provide flexibility for MIPS eligible clinicians whose data are inaccurate, unusable, or otherwise compromised due to circumstances outside the control of clinicians and their agents. We did not develop this policy to hold harmless third party intermediaries or other agents for any role they play in data inaccuracies. CMS does not have authority to waive liability as it relates to fraud, waste, and abuse laws or to alter the certification requirements of health information technology. Furthermore, we plan to share information as appropriate with law enforcement and with ONC to the extent we learn of concerns involving CEHRT, as defined at § 414.1305. We also note that third party intermediaries that submit data that are inaccurate, unusable or otherwise compromised may be subject to remedial action or termination in accordance with § 414.1400(f).

Comment: One commenter suggested that CMS apply this policy when MIPS eligible clinicians or third party intermediaries become aware of relevant information prior to the end of the MIPS data submission period, because doing so would encourage MIPS eligible clinicians, health IT vendors, and third party intermediaries to inform CMS of relevant information in a timely manner. One commenter suggested that CMS consider the timing of the discovery of the compromised data when making a determination of whether to apply reweighting.

Response: We agree that MIPS eligible clinicians and third party intermediaries should alert CMS of relevant information in a timely manner. If a MIPS eligible clinician with compromised data requests reweighting under this policy, we would consider both the timing of when the clinician learned the data were compromised and the state of the data to determine whether reweighting is appropriate. We believe there may be some circumstances where a MIPS eligible clinician learns that their data is inaccurate, unusable, or otherwise compromised before the end of the data submission period and the source data is unaffected. In these instances, we believe the MIPS eligible clinician should explore alternatives and if possible submit data that are uncompromised.

Comment: One commenter supported our proposal to limit the policy to information we learn of prior to the beginning of the applicable MIPS payment year.

Response: We thank the commenter for their support of our proposal.

Comment: One commenter requested that we ensure the terms ''any individual or entity'' within the definition of ''agent'' for purposes of this policy include practice staff, billing vendors, practice vendors, consultants, chart abstractors, and the like because these entities are often the root cause of data errors or incomplete reporting.

Response: We proposed that the term agent include any individual or entity, including a third party intermediary as described in § 414.1400, acting on behalf of or under the instruction of the MIPS eligible clinician (84 FR 40796). In reviewing individual circumstances to determine if reweighting is warranted, we will consider the specific circumstances that led to data being inaccurate, unusable, or otherwise compromised and will consider whether individuals or entities involved in the data errors were working in a capacity within the control of the clinician and whether quality control processes should have been in place to prevent errors.

Comment: One commenter requested that we extend the policy into the payment year for instances when the MIPS eligible clinician learns about the data issue after receiving payment adjustments.

Response: We continue to believe it is appropriate to apply reweighting only in cases when we learn of the compromised data before the beginning of the associated MIPS payment year because we want to encourage MIPS eligible clinicians and their agents to inform us of these concerns in a timely manner so we can update our data sets timely, while minimizing the impacts to other stakeholders who utilize MIPS data.

After consideration of the comments we received, we are finalizing our proposal at § 414.1380(c)(2)(i)(A)(9) and (c)(2)(i)(C)(10) to, beginning with the 2018 MIPS performance period and 2020 MIPS payment year, reweight the performance categories for a MIPS eligible clinician we determine has data for a performance category that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents if we learn the relevant information prior to the beginning of the associated MIPS payment year. In addition, we are finalizing our proposed amendment to § 414.1380(c)(2)(i)(C) to ensure that the reweighting at § 414.1380(c)(2)(i)(C)(10) will not be voided by the submission of data for the Promoting Interoperability performance category.

We note that we previously finalized at § 414.1380(c) that if a MIPS eligible

clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77326 through 77328 and 82 FR 53778 through 53779). Therefore, if a MIPS eligible clinician is scored on fewer than two performance categories as a result of reweighting due to compromised data, he or she would receive a final score equal to the performance threshold.

(iii) Redistributing Performance Category Weights

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77325 through 77329 and 82 FR 53783 through 53785, 53895 through 53900), in the CY 2019 PFS final rule (83 FR 59876 through 59878), and at § 414.1380(c)(2)(ii), we established policies for redistributing the weights of performance categories for the 2019, 2020, and 2021 MIPS payment years in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories. Under these policies, we generally redistribute the weight of a performance category or categories to the quality performance category because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs.

In the CY 2020 PFS proposed rule (84 FR 40798), we discussed our belief that it would not be appropriate to redistribute weight from the other performance categories to the cost performance category for the 2022 MIPS payment year, except in scenarios in which the only other scored performance category is the improvement activities performance category. We noted that we had proposed substantial changes to the MSPB and total per capital cost measures, as well as adding 10 new episode-based measures (84 FR 40753 through 40762). We stated that we believed it is appropriate to provide MIPS eligible clinicians additional time to adjust to these changes prior to redistributing weight to the cost performance category. Under the proposals we made in the proposed rule, as described in more detail below, we would begin to redistribute more weight to the cost performance category beginning with the 2023 MIPS payment year, because MIPS eligible clinicians will have had more experience being scored on cost measures at that point, and will have had time to adjust to the changes to existing measures and new episode-based measures that we proposed.

Beginning with the 2022 MIPS payment year, we proposed to not redistribute performance category weights to the improvement activities performance category in any scenario (84 FR 40798). For the improvement activities performance category, we are only assessing whether a MIPS eligible clinician completed certain activities (83 FR 59876 through 59878). Because MIPS eligible clinicians will have had several years of experience reporting under MIPS, we stated that we believe it is important to prioritize performance on measures that show a variation in performance, rather than the activities under the improvement activities performance category, which are based on attestation of completion. Therefore, we stated that we believe it is no longer appropriate to increase the weight of the improvement activities performance category above 15 percent under our redistribution policies. We noted that in situations where the weights of both the quality and Promoting Interoperability performance categories are redistributed, cost would be weighted at 85 percent and improvement activities would be weighted at 15 percent. We stated that we believe this would help to reduce incentives to not report measures for the quality performance category in circumstances when a clinician may be able to report but chooses not to do so. For example, when a clinician may be able to report on quality measures, but chooses not to report because they are located in an area affected by extreme and uncontrollable circumstances as identified by CMS and qualify for reweighting under § 414.1380(c)(2)(i)(A)(8).

For the 2022 MIPS payment year, we proposed at § 414.1380(c)(2)(ii)(D) similar redistribution policies to our policies finalized for the 2021 MIPS payment year (83 FR 59876 through 59878), with minor modifications, as shown in Table 54 (84 FR 40798). First, we adjusted our redistribution policies to account for a cost performance category weight of 20 percent for the 2022 MIPS payment year. We also proposed, in scenarios when the cost performance category weight is redistributed while the Promoting Interoperability performance category weight is not, to redistribute a portion of the cost performance category weight to the Promoting Interoperability performance category, as well as to the quality performance category. We stated that we believe this is appropriate given our current focus on working with the Office of the National Coordinator for Health IT (ONC) on implementation of the interoperability provisions of the 21st Century Cures Act (the Cures Act) (Pub. L. 115–233, enacted December 13, 2016) to ensure seamless but secure exchange of health information for clinicians and patients. While we have previously redistributed all of the cost performance category weight to the quality performance category (83 FR 59876 through 59878), we proposed to redistribute 15 percent to the quality performance category and 5 percent to the Promoting Interoperability performance category for the 2022 MIPS payment year (*see* Table 54). This proposed change would emphasize the importance of interoperability without overwhelming the contribution of the quality performance category to the final score. We also proposed to weight the improvement activities performance category at 15 percent and to weight the Promoting Interoperability performance category at 85 percent for the 2022 MIPS payment year when the quality and cost performance categories are each weighted at zero percent, to align with our focus on interoperability and pursuant to our proposal of not redistributing weight to the improvement activities performance category (84 FR 40798).

TABLE 54: Performance Category Redistribution Policies Proposed for the 2022 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	40%	20%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	65%	20%	15%	0%
-No Quality	0%	20%	15%	65%
-No Improvement Activities	55%	20%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	85%	15%	0%
-No Promoting Interoperability and no Improvement Activities	80%	20%	0%	0%
-No Quality and no Improvement Activities	0%	20%	0%	80%

We received public comments on our proposed redistribution policies for the 2022 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to generally not redistribute weight to the cost performance category for the 2022 MIPS payment year.

Response: We appreciate the commenters' support. We are finalizing this policy with a minor modification, which is discussed in more detail below, to decrease the amount of weight redistributed to the cost performance category when the cost and improvement activities performance categories are the only performance categories scored.

Comment: Several commenters expressed concern with our proposal to no longer redistribute weight to the improvement activities performance category and in particular expressed concern when only cost and improvement activities performance categories are scored because cost would be 85 percent of the final score. Commenters also stated that it will not necessarily be a rare occurrence for a MIPS eligible clinician to be scored on only cost and improvement activities, and expressed concerns with the attribution methodologies used in cost measures. A few commenters expressed concerns about redistributing to the cost category due to issues with cost measures, such as attribution, reliability, and actionability. Commenters further noted that cost measures are fairly new and even those with which they have had experience (TPCC and MSPB) were having major updates to their specifications. One commenter did not agree with our assertion that this policy would reduce incentives to not report measures for the quality performance category, but did not provide further details. One commenter stated that the Quality Payment Program should focus on performance categories that support quality improvement, such as the improvement activities performance category, rather than on the cost performance category, because quality improvement is so important for patient care.

Response: We agree with commenters that the improvement activities performance category reflects important aspects of quality improvement and performance. However, we do have concerns with redistributing a substantial portion of the performance category weights to the improvement activities performance category due to a lack of variability in performance for this category, and we continue to believe that we should not redistribute weight to the improvement activities performance category. However, we agree with commenters that a weight of 85 percent for the cost performance category is not appropriate for the 2022 MIPS payment year. As noted in section III.K.3.c.(2)(b) of this final rule, opportunities to improve performance in the cost performance category are somewhat dependent on the performance feedback on cost measures we are able to provide. As we have provided detailed feedback on the cost measures for the first time during the 2019 performance period and expect to provide detailed feedback on new and revised cost measures for the first time during the 2020 performance period, we believe that we should not weight the cost performance category so heavily for the 2022 MIPS payment year. We believe that weighting the cost and improvement activities performance categories each at 50 percent would appropriately balance our concerns with redistributing weight to the improvement activities performance category and the concerns raised by commenters with a weight of 85 percent for the cost performance category.

Comment: One commenter stated that our current reweighting policies put undue emphasis on the quality performance category, and suggested that CMS redistribute weight evenly to the quality and improvement activities performance categories, especially for non-patient facing clinicians who may lack applicable measures and are spending valuable time performing quality improvement activities for the improvement activities performance category.

Response: Under our existing policies, we have generally redistributed weight to the quality performance category. The quality performance category is a critical component of value-based care, and therefore, we believe performance

on quality measures is important. In addition, there is variation in performance for the quality performance category, but for the improvement activities we are only assessing whether the MIPS eligible clinician completed activities. Finally, we believe that redistributing weight to the quality performance category would encourage MIPS eligible clinicians to report on quality measures as a zero score for this performance category would have more significant impact. However, over time, we want to redistribute more weight to the cost and Promoting Interoperability performance categories, and less to the quality performance category, to have better alignment between the cost and quality performance categories and due to our focus on interoperability. In general, we want to avoid redistributing weight to the improvement activities performance category because we believe other performance categories can better identify variation in performance.

Comment: One commenter stated that it is appropriate to delay the redistribution of more weight to the Promoting Interoperability performance category while ONC and other stakeholders work to make functional interoperability a reality.

Response: We thank the commenter for sharing their concern, but we continue to believe it is appropriate to increase the amount of weight redistributed to the Promoting Interoperability performance category in order to align with our focus on interoperability.

After consideration of the comments we received, we are finalizing our redistribution policies for the 2022 MIPS payment year at § 414.1380(c)(2)(ii)(D) as proposed with a few modifications. In sections III.K.3.c.(1)(b) and III.K.3.c.(2)(a) of this final rule, we are finalizing different generally applicable weights for the quality and cost performance categories, respectively, than what we proposed. For the 2022 MIPS payment year, we are finalizing a quality performance category weight of 45 percent (instead of 40 percent as proposed) and a cost performance category weight of 15 percent (instead of 20 percent as proposed). Accordingly, we are modifying the numerical amounts of weight that we will redistribute to account for these different weights for quality and cost, as shown in Table 55. In addition, in the scenario when only the improvement activities and cost performance categories are scored, we will provide a weight of 50 percent for each performance category, as shown in Table 55.

TABLE 55: Performance Category Redistribution Policies Finalized for the 2022 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	45%	15%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	70%	15%	15%	0%
-No Quality	0%	15%	15%	70%
-No Improvement Activities	60%	15%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	85%	15%	0%	0%
-No Quality and no Improvement Activities	0%	15%	0%	85%

In the CY 2020 PFS proposed rule, we proposed weights for the cost performance category of 25 and 30 percent for the 2023 and 2024 MIPS payment years, respectively (84 FR 40752 through 84 FR 40753). Because MIPS eligible clinicians will have had more experience being scored on cost measures, we stated that we believe it would be appropriate to begin redistributing even more of the performance category weights to the cost performance category beginning with the 2023 MIPS payment year. While we proposed to redistribute weight to the cost performance category for the 2022 MIPS payment year in scenarios in which only the cost and improvement activities performance categories are scored, we stated that we believe that we should redistribute weight to the cost performance category in other scenarios beginning with the 2023 MIPS payment year. We stated that in general, we would redistribute performance category weights so that the quality and cost performance categories are almost equal. For simplicity, we would redistribute the weight in 5-point increments. If the redistributed weight cannot be equally divided between quality and cost in 5-point increments, we would redistribute slightly more weight to quality than cost. We stated that we believe that redistributing weight equally to quality and cost is consistent with our goal of greater alignment between the quality and cost performance categories (84 FR 40797 through 40798). We stated that we would also continue to redistribute weight to the Promoting Interoperability

performance category, but we would ensure that if the quality and cost performance categories are scored, they would have a higher weight than the Promoting Interoperability performance category. For example, beginning with the 2024 MIPS payment year, if the improvement activities performance category is the only performance category to be reweighted to zero percent, quality and cost would be 40 and 35 percent, respectively, and we would not increase the weight of the Promoting Interoperability performance category (weighted at 25 percent) so that it would not exceed the weight of the quality or cost performance categories. Our proposed redistribution polices for the 2023 and 2024 MIPS payment years, which we proposed to codify at § 414.1380(c)(2)(ii)(E) and (F), are presented in Tables 56 and 57.

TABLE 56: Performance Category Redistribution Policies Proposed for the 2023 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	35%	25%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	50%	35%	15%	0%
-No Quality	0%	40%	15%	45%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	65%	0%	0%	35%
-No Promoting Interoperability and no Quality	0%	85%	15%	0%
-No Promoting Interoperability and no Improvement Activities	55%	45%	0%	0%
-No Quality and no Improvement Activities	0%	45%	0%	55%

TABLE 57: Performance Category Redistribution Policies Proposed for the 2024 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	45%	40%	15%	0%
-No Quality	0%	45%	15%	40%
-No Improvement Activities	40%	35%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	60%	0%	0%	40%
-No Promoting Interoperability and no Quality	0%	85%	15%	0%
-No Promoting Interoperability and no Improvement Activities	50%	50%	0%	0%
-No Quality and no Improvement Activities	0%	60%	0%	40%

We received public comments on our proposed redistribution policies for the 2023 and 2024 MIPS payment years. The following is a summary of the comments we received and our responses.

Comment: Several commenters did not support our proposal to begin to redistribute weight to the cost performance category in any scenario. Commenters indicated that, as CMS adds more measures to the cost performance category, more measures will be in their first or second year of use. Furthermore, one commenter expressed concern that cost measures exclude Part D costs. Another commenter believed other performance categories have a stronger focus on care quality because they measure aspects of care improvement rather than resource use. Another commenter believed that MIPS eligible clinicians who receive reweighting for the promoting interoperability performance category are often in small and/or rural practices with limited resources, and increasing the weight of the cost performance category would place them at a greater disadvantage.

Response: As described in sections III.K.3.c.(1)(b) and III.K.3.c.(2)(a) of this final rule, we are not finalizing weights for the cost and quality performance categories for the 2023 and 2024 MIPS payment years. Instead, we have decided to maintain the weight of the cost performance category at 15 percent for the 2022 MIPS payment year and address its weight for the 2023 and 2024 MIPS payment years in future rulemaking. As a result, we have decided not to finalize redistribution policies for the 2023 and 2024 MIPS payment years because we have not established the generally applicable weights for these years. However, we will take these comments into consideration in future rulemaking.

After consideration of public comments, we are no longer finalizing performance category weights for the 2023 and 2024 MIPS payment years. Therefore, we are no longer finalizing weights for the cost and quality performance categories for the 2023 and 2024 MIPS payment years.

e. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score used in MIPS payment adjustment calculations, we refer readers to the CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799) and CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343).

In the CY 2020 PFS proposed rule (84 FR 40800 through 40804), we proposed to: (1) Set the performance threshold for the 2022 and 2023 MIPS payment years and (2) set the additional performance threshold for exceptional performance for the 2022 and 2023 MIPS payment years.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act includes a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies. The performance thresholds for the first 3 years of MIPS are presented in Table 58.

TABLE 58—PERFORMANCE THRESHOLDS FOR THE 2019 MIPS PAYMENT YEAR, 2020 MIPS PAYMENT YEAR, AND 2021 MIPS PAYMENT YEAR

	2019 MIPS payment year (points)	2020 MIPS payment year (points)	2021 MIPS payment year (points)
Performance Threshold	3	15	30

To determine a performance threshold to propose for the fourth year of MIPS (2020 MIPS performance period/2022 MIPS payment year) and the fifth year of MIPS (2021 MIPS performance period/2023 MIPS payment year), in the CY 2020 PFS proposed rule (84 FR 40801), we again relied upon the special rule in section 1848(q)(6)(D)(iii) of the Act, as amended by 51003(a)(1)(D) of the Bipartisan Budget Act of 2018.

As required by section 1848(q)(6)(D)(iii) of the Act, we considered data available from a prior period with respect to performance on measures and activities that may be used under the MIPS performance categories. In accordance with clause (iv) of section 1848(q)(6)(D) of the Act, we also considered which data could be used to estimate the performance threshold for the 2024 MIPS payment year to ensure a gradual and incremental transition from the performance threshold we would establish for the 2022 MIPS payment year. In accordance with section

1848(q)(6)(D)(i) of the Act, the performance threshold for the 2024 MIPS payment year will be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

As noted in the CY 2020 PFS proposed rule (84 FR 40801), to estimate the performance threshold for the 2024 MIPS payment year, we considered the actual MIPS final scores for MIPS eligible clinicians for the 2019 MIPS payment year and the estimated MIPS final scores for the 2020 MIPS payment year and 2021 MIPS payment year. We analyzed the actual final scores for the first year of MIPS (the 2019 MIPS payment year) and found the mean final score was 74.01 points and the median final score was 88.97 points, as described in the CY 2019 PFS final rule (83 FR 59881). In the Regulatory Impact Analysis of the CY 2019 PFS final rule, we used data submitted for the first year of MIPS (2017 MIPS performance period/2019 MIPS payment year) and applied the scoring and eligibility policies for the third year of MIPS (2019 MIPS performance period/2021 MIPS payment year) to estimate the potential final scores for the 2021 MIPS payment year. The estimated mean final score for the 2021 MIPS payment year was 69.53 points and the median final score was 78.72 points (83 FR 60048). We also estimated mean and median final scores for the 2020 MIPS payment year of 80.3 points and 90.91 points, respectively, based on information in the Regulatory Impact Analysis in the CY 2018 Quality Payment Program final rule (82 FR 53926 through 53950). Specifically, we used 2015 and 2016 PQRS data, 2014 and 2015 CAHPS for PQRS data, 2014 and 2015 VM data, 2015 and 2016 Medicare and Medicaid EHR Incentive Program data, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility, the initial QP determination file for the 2019 MIPS payment year, the 2017 MIPS measure benchmarks, and other available data to model the final scores for clinicians estimated to be MIPS eligible in the 2020 MIPS payment year (82 FR 53930). In the CY 2020 PFS proposed rule, we considered using the actual final scores for the 2020 MIPS payment year; however, the data used to calculate the final scores was submitted through the first quarter of 2019, and final scores for MIPS eligible clinicians were not available in time for us to use in our analyses for purposes of the proposed rule; we stated our intention to include those results in the final rule if available (84 FR 40801). We believed the data points based on actual data from the 2017 MIPS performance period/2019 MIPS payment year were appropriate to use in our analysis in projecting the estimated performance threshold for the 2024 MIPS payment year. However, we also noted that after we analyze the actual final scores for the 2020 MIPS payment year, if we see the mean or median final scores significantly increasing or decreasing, we will consider modifying our estimation of the performance threshold for the 2024 MIPS payment year accordingly. Table 51 of the CY 2020 PFS proposed rule summarized the different estimated performance thresholds for the 2024 MIPS payment year (84 FR 40802).

In the CY 2020 PFS proposed rule, we chose the mean final score of 74.01 points for the 2019 MIPS payment year as our estimate of the performance threshold for the 2024 MIPS payment year because it represents a mean based on actual data; is more representative of clinician performance because all final scores are considered in the calculation; is more achievable for clinicians, particularly for those that are new to MIPS; and is a value that falls generally in the middle of potential values for the performance threshold referenced in Table 51 in the CY 2020 PFS proposed rule (84 FR 40802). In the CY 2019 PFS proposed rule (83 FR 35972), we had requested comment on our approach to estimating the performance threshold for the 2024 MIPS payment year, which was based on the estimated mean final score for the 2019 MIPS payment year, and whether we should use the median instead of the mean. A summary of comments was included in CY 2020 PFS proposed rule (84 FR 40802).

We noted that estimating the performance threshold for the 2024 MIPS payment year based on the mean final score for the 2019 MIPS payment year is only an estimation that we are providing in accordance with section 1848(q)(6)(D)(iv) of the Act. We proposed to use data from the 2019 MIPS payment year because it was the only MIPS final score data available and usable in time for the publication of the CY 2020 PFS proposed rule (84 FR 40802).

We anticipated that the mean and median data points for the 2020 MIPS payment year would be available for consideration prior to publication of the final rule and solicited comment on whether and how we should use this information to update our estimates.

Since the publication of the CY 2020 PFS proposed rule, we now have the actual final score data for the 2020 MIPS payment year with which to estimate the mean and median. We note these values are estimates and that the mean and median may change as we finish the targeted review process for the 2020 MIPS payment year. In addition, we anticipate that the scores of some MIPS eligible clinicians may change as a result of the policy that we are finalizing in section III.K.3.d.(2)(b)(ii)(A) of this final rule to reweight the performance categories for a MIPS eligible clinician due to compromised data. We estimate the mean of the actual final scores for the 2020 MIPS payment year at 86.91 points and the median at 99.63 points although, again, the values may change after the completion of targeted reviews and due to the reweighting policy for data that are inaccurate, unusable, or otherwise compromised. We noted in the CY 2020 PFS proposed rule (84 FR 40802) some policies which could increase final scores. For example, beginning with the 2020 MIPS payment year, we increased the low-volume threshold compared to the 2019 MIPS payment year. We also added incentives for improvement scoring for the quality performance category and bonuses for complex patients and small practices.

We refer readers to Table 59 for potential values for estimating the performance threshold for the 2024 MIPS payment year based on the mean or median final score from prior periods. We have updated this table from the CY 2020 PFS proposed rule (84 FR 40802) to include the actual final score data for the 2020 MIPS payment year. We have also updated this table to include an estimate of the mean and median for the 2022 MIPS payment year from our Regulatory Impact Analysis in section VII.F.10. of this final rule as this estimate incorporates the newly available data for the 2020 MIPS payment year.

TABLE 59—POTENTIAL VALUES FOR ESTIMATED PERFORMANCE THRESHOLD FOR THE 2024 MIPS PAYMENT YEAR BASED ON THE MEAN OR MEDIAN FINAL SCORE FOR THE 2019 MIPS PAYMENT YEAR, 2020 MIPS PAYMENT YEAR, 2021 MIPS PAYMENT YEAR, AND 2022 MIPS PAYMENT YEAR

	2019 MIPS payment year * (points)	2020 MIPS payment year ** (points)	2021 MIPS payment year *** (points)	2022 MIPS payment year *** (points)
Mean Final Score	74.01	86.91	69.53	76.67
Median Final Score	88.97	99.63	78.72	83.57

* Mean and median final scores based on actual final scores for the 2019 MIPS payment year as published in CY 2019 PFS final rule RIA (83 FR 60048).

** Mean and median final scores based on actual final scores for the 2020 MIPS payment year. Mean and median may change after the completion of targeted reviews and due to the reweighting policy for data that are inaccurate, unusable, or otherwise compromised.

*** Mean and median final scores based on estimated final scores for the 2021 MIPS payment year as published in CY 2019 PFS final rule RIA (83 FR 60048) and the 2022 MIPS payment year as estimated in section VII. of this final rule.

We noted in the CY 2020 PFS proposed rule (84 FR 40801 through 40802) that we would analyze the actual final scores for the 2020 MIPS payment year, and because the data is now available and usable, we have updated our analyses. As illustrated in Table 59, we found the mean and median final scores for the 2020 MIPS payment year are higher than the values for the 2019 MIPS payment year and higher than our original estimate from the CY 2020 PFS proposed rule which had an estimated mean of 80.30 and median of 90.91 (84 FR 40802); however, we also estimated the final scores for the 2021 MIPS payment year will be lower than the values for both the 2019 and 2020 MIPS payment years.

In the CY 2020 PFS proposed rule (84 FR 40802), we noted that using final scores from the early years of MIPS has numerous limitations and may not be similar to the distribution of final scores for the 2024 MIPS payment year. Recognizing the limitations of data for the 2019 MIPS payment year and the 2020 MIPS payment year, we requested comments in the CY 2020 PFS proposed rule on whether we should update or modify our estimates (84 FR 40802).

We proposed a performance threshold of 45 points for the 2022 MIPS payment year and a performance threshold of 60 points for the 2023 MIPS payment year to be codified at § 414.1405(b)(7) and (8), respectively. A performance threshold of 45 points for the 2022 MIPS payment year and 60 points for the 2023 MIPS payment year would be an increase that is consistent with the increase in the performance threshold from the 2020 MIPS payment year (15 points) to the 2021 MIPS payment year (30 points), and we believe it would allow for a consistent increase over time that provides a gradual and incremental transition to the performance threshold we will establish for the 2024 MIPS payment year, which we estimated in the CY 2020 PFS proposed rule (84 FR 40802) to be 74.01 points.

In the CY 2020 PFS proposed rule (84 FR 40802), we provided the example that if in future rulemaking we were to set the performance threshold for the 2024 MIPS payment year at 75 points (which is close to the mean final score for the 2019 MIPS payment year), this would represent an increase in the performance threshold of approximately 45 points from the 2021 MIPS payment year (that is, the difference from the Year 3 performance threshold of 30 points to a Year 6 performance threshold of 75 points). We stated that we believe an increase of approximately 15 points each year, from Year 3 through Year 6 of the MIPS program, would provide for a gradual and incremental transition toward a performance threshold that must be set at the mean or median final score for a prior period in Year 6 of the MIPS program (84 FR 40802).

We stated that we also believe this increase of 15 points per year could incentivize higher performance by MIPS eligible clinicians and that a performance threshold of 45 points for the 2022 MIPS payment year, and a performance threshold of 60 points for the 2023 MIPS payment year, represent a meaningful increase compared to 30 points for the 2021 MIPS payment year, while maintaining flexibility for MIPS eligible clinicians in the pathways available to achieve this performance threshold (84 FR 40802). In the CY 2020 PFS proposed rule (84 FR 40807 through 40809), we provided examples of the ways clinicians can meet or exceed the proposed performance threshold for the 2022 MIPS payment year.

We recognized that some MIPS eligible clinicians may not exceed the proposed performance thresholds either due to poor performance or by failing to report on an applicable measure or activity that is required (84 FR 40803). We also recognized the unique challenges for small practices and rural clinicians that could prevent them from meeting or exceeding the proposed performance thresholds and sought feedback in the proposed rule on the participation of small and rural practices in MVPs (84 FR 40740).

We invited public comment on our proposals to set the performance threshold for the 2022 MIPS payment year at 45 points and to set the performance threshold for the 2023 MIPS payment year at 60 points. We also solicited comment on whether we should adopt a different performance threshold in this final rule if we determine that the actual mean or median final scores for the 2020 MIPS payment year are higher or lower than our estimated performance threshold for the 2024 MIPS payment year of 74.01 points. We anticipated the data will change over time and that the distribution of final scores will differ from one year to the next. We also solicited comment on whether the increase should be more gradual for the 2022 MIPS payment year, which would mean a lower performance threshold (for example, 35 instead of 45 points), or whether the increase should be steeper (for example, 50 points). We also solicited comment on alternative numerical values for the performance threshold for the 2022 MIPS payment year. For the 2023 MIPS payment year, we alternatively considered whether the performance threshold should be set at a lower or higher number, for example, 55 points or 65 points, and also solicited comment on alternative numerical values for the performance threshold for the 2023 MIPS payment year.

We received public comments on our proposals to set the performance threshold at 45 points for the 2022 MIPS payment year and at 60 points for the 2023 MIPS payment year. We also received public comments on whether the performance threshold for the 2022

MIPS payment year and the 2023 MIPS payment year should be higher or lower; whether we should adopt alternative numerical values for the performance threshold for the 2022 MIPS payment year and the 2023 MIPS payment year; and whether we should adopt a different performance threshold in this final rule if we determine that the actual mean or median final scores for the 2020 MIPS payment year are higher or lower than the 74.01 points estimated for the 2024 MIPS payment year.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed performance thresholds. Several commenters believed that the higher performance thresholds are a reasonable and gradual increase; would encourage participation; motivate clinicians to improve health care quality; hold clinicians accountable for quality and cost; ensure the incentives are conveyed to those clinicians who are attaining the thresholds needed to continually provide high quality health care for all patients; and would benefit clinicians in the transition to value-based payment. One commenter indicated that the proposal should give more genuinely high-quality clinicians meaningful bonuses, which in the past have been small due to MIPS policies and budget neutrality requirements.

Response: We agree that MIPS should incentivize clinicians to perform at a high level and support their transition to value-based care and believe that raising the performance threshold helps accomplish that goal. In addition, as discussed in section III.K.3.e.(3) of this final rule, we are raising the additional performance threshold to recognize and incentivize clinicians that provide high value care.

Comment: A few commenters did not support the proposed performance threshold of 45 points for the 2022 MIPS payment year believing that current policies and clinician participation levels make it impossible for high performing clinicians to achieve the advertised positive adjustment and receive a meaningful incentive for participation in MIPS. One commenter also expressed concerns that MIPS reporting requires investments in technology, staffing, as well as adjustments to workflows to meet quality measure requirements throughout the year and that practices committed to quality care and performing at exceptional levels receive adjustments of less than two percent for reaching the highest levels of MIPS scoring. Another commenter stated that the proposed performance thresholds and the low-volume threshold lead to an unsustainable distribution of scores.

Response: We recognize that, due to statutory requirements of budget neutrality and the application of a scaling factor, high performers may receive payment adjustments that are different than the applicable percent for the year provided in the statute (for example, 9 percent for the 2022 MIPS payment year). While a higher performance threshold may enlarge the estimated decrease in aggregate allowed charges resulting from the application of negative MIPS payment adjustment factors, and therefore, may increase the scaling factor, we believe the proposed performance thresholds of 45 points for the 2022 MIPS payment year and 60 points for the 2023 MIPS payment year would encourage movement toward value-based care with a focus on the delivery of high quality care for Medicare beneficiaries and provide a gradual and incremental transition to the estimated performance threshold for the 2024 MIPS payment year, as required by the statute. We also believe that the additional performance threshold for exceptional performance discussed later in section III.K.3.e.(3) of this final rule provides an additional financial incentive for high performers and will continue to incentivize their exceptional performance.

Comment: A few commenters did not support adopting a different performance threshold than the proposed performance thresholds of 45 points and 60 points, for the 2022 and 2023 MIPS payment years, respectively, if the actual mean or median final scores for the 2020 MIPS payment year are higher than the estimated performance threshold of 74.01 points for the 2024 MIPS payment year. One commenter recommended that the performance threshold should not increase even if the actual scores for the 2018 MIPS performance period are higher than expected. One commenter recommended lowering the performance threshold, or, alternatively, not increasing it and cited concern for small practices.

Response: We thank the commenters for their suggestions. Since the publication of the CY 2020 PFS proposed rule, the actual final score data for the 2020 MIPS payment year have become available and usable. For the 2020 MIPS payment year, the calculated mean and median of the actual final scores are 86.91 points and 99.63 points, respectively (although the mean and median may change after the completion of targeted reviews and due to the reweighting policy for data that are inaccurate, unusable, or otherwise compromised). Those mean and median final scores are higher than our estimates of 80.30 for the mean and 90.91 for the median that we included in Table 51 of the CY 2020 PFS proposed rule (84 FR 40802). We noted in the CY 2020 PFS proposed rule (84 FR 40801) that after we analyze the actual final scores for the 2020 MIPS payment year, if the mean or median final scores are significantly higher or lower, we will consider modifying our estimation of the performance threshold for the 2024 MIPS payment year. In considering whether to modify our estimate of the performance threshold for the 2024 MIPS payment year, we took into account how the actual mean and median final scores for the 2019 and 2020 MIPS payment years align with the projected mean and median final scores for 2021 and 2022 MIPS payment years and considered the differences in the eligibility and scoring policies for the different MIPS payment years.

We note that our original estimates for the 2020 MIPS payment year were lower than the actual values for the 2020 MIPS payment year. The difference in actual versus estimated values for the 2020 MIPS payment year may be partially due to the data sources available for estimates at that time. The estimates for the 2020 MIPS payment year were created using data from legacy programs, such as the Physician Quality Reporting System (PQRS) and the Value Modifier and the models applied participation assumptions (82 FR 53926 through 53948). In contrast, the estimated final scores for the 2021 and 2022 MIPS payment years incorporate data that were submitted for MIPS. These estimates also have limitations and assumptions; however, we believe that using MIPS submission data provides a better approximation of potential MIPS participation and performance. Specifically, for the 2021 MIPS payment year, we estimated final scores using primarily data submitted for MIPS for the 2017 MIPS performance period, including data submitted for the quality, improvement activities, and Promoting Interoperability (which was called advancing care information for the 2017 MIPS performance period) performance categories. For the 2022 MIPS payment year, we updated the analysis to include information submitted for the 2018 MIPS performance period. In addition to using MIPS submission data, we integrated additional data sources: CAHPS for MIPS and CAHPS for ACOs, the total per capita cost measure, Medicare

Spending Per Beneficiary (MSPB) clinician measure, the episode-based measures and other data sets. For a complete description of the data sources and our methodology to estimate the 2021 MIPS payment year final scores, please refer to the Regulatory Impact Analysis in the CY 2019 PFS final rule (83 FR 60046 through 83 FR 60059). For a complete description of the data sources and methodology for the projected 2022 MIPS payment year final scores, please refer to the Regulatory Impact Analysis in section VII. of this final rule.

When we compare the actual mean and median scores from the 2019 and 2020 MIPS payment years to the projected mean and median scores for the 2021 and 2022 MIPS payment years (see Table 59), we see that the 2020 MIPS payment year mean final score of 86.91 is higher than the projected mean final scores for the 2021 and 2022 MIPS payment years (69.53 and 76.67, respectively). In contrast, the mean result for the 2019 MIPS payment year (74.01) falls between the projected means for the 2021 and 2022 MIPS payment years (69.53 and 76.67, respectively). The median actual values for both the 2019 and 2020 MIPS payment years are higher than the projected median values for the 2021 and 2022 MIPS payment years.

In addition to comparing the actual and estimated mean and median final scores across different payment years, we also considered the policy differences across the different MIPS payment years. We stated in the CY 2020 PFS proposed rule (84 FR 40802) that we understood using final scores from the early years of MIPS had numerous limitations. We also noted that the distribution of final scores for the 2024 MIPS year may be different from the early years due to eligibility and scoring policy changes. For example, beginning with the 2020 MIPS payment year, we increased the low-volume threshold compared to the 2019 MIPS payment year. We also added incentives for improvement scoring for the quality performance category and bonuses for complex patients and small practices, which could increase scores. Starting with the 2021 MIPS payment year, we modified our eligibility to include new clinician types and an opt-in policy, revised the small practice bonus, significantly revised the Promoting Interoperability performance category scoring methodology, and added a topped-out cap for certain topped out quality measures. In addition, the performance category weights changed each payment year which limits the comparability of the actual mean or median final scores from either the 2019 or 2020 MIPS payment year to future payment year performance.

Given these concerns, and based on feedback from commenters, we have decided to take a conservative approach for estimating the 2024 MIPS payment year performance threshold. We believe the policy changes across MIPS payment years, in conjunction with the projected decrease in mean and median final scores from the 2020 MIPS payment year, justifies using the mean from the 2019 MIPS payment year (74.01 points) as the estimated performance threshold for the 2024 MIPS payment year. Despite differences in policies for the 2019 MIPS payment year compared to later MIPS payment years, this value is the lowest of all the actual mean final scores and falls between the projected mean final scores for the 2021 and 2022 MIPS payment year. If we increase our estimated performance threshold for the 2024 MIPS payment year based on the actual scores for the 2020 MIPS payment year (and accordingly increase the performance threshold for 2022 and 2023 MIPS payment years), then we may be forcing a transition that may not be gradual and incremental. As discussed further in our responses to comments, we are finalizing the performance thresholds for the 2022 and 2023 MIPS payment years as proposed, but we may revisit the performance threshold for the 2023 MIPS payment year in future rulemaking if we receive additional data that changes our estimate of the performance threshold for the 2024 MIPS payment year.

Comment: A few commenters expressed concerns with the use of data from the 2017 MIPS performance period and 2019 MIPS payment year to set the performance threshold at 45 points stating that data from the 2017 MIPS performance period is not an accurate representation of current actual performance because of policy changes to the MIPS program; is based on one year of data that is not indicative of performance in the future; and that the threshold is too high for small practices. Commenters recommended that CMS instead focus on ensuring stability and participation in MIPS.

Response: We appreciate the need to ensure relevant data are used to develop performance thresholds. As discussed in the previous response, we also agree that there are limitations with using final scores from the early years of MIPS (including the 2017 MIPS performance period which is associated with the 2019 MIPS payment year). We have considered all available data and found that the mean of 74.01 points for the 2019 MIPS payment year is the lowest of the two actual mean scores available and is close to our projections for mean final scores for the 2021 and 2022 MIPS payment years illustrated in Table 59. Therefore, we believe that 74.01 points is an appropriate estimate for a performance threshold for the 2024 MIPS payment year. We also believe the proposed performance thresholds of 45 points and 60 points for the 2022 and 2023 MIPS payment years, respectively, are appropriate because they would represent a gradual and incremental transition to the estimated performance threshold for the 2024 MIPS payment year, as required by the statute. We may revisit the performance threshold for the 2023 MIPS payment year in future rulemaking if we determine there is additional data to suggest our estimate should be modified.

We acknowledge the concerns regarding the potential burden on small practices. There are special policies available for small practices such as the small practice bonus and special scoring for the improvement activities performance category, and the availability of customized technical assistance through the Small, Underserved, and Rural Support Initiative to assist clinicians in small practices. Finally, we note that we expect a majority of clinicians in all practice sizes will receive a positive payment adjustment if they participate in MIPS. As shown in Table 123 within the Quality Payment Program section of the Regulatory Impact Analysis in section VII. of this final rule, 92.5 percent of clinicians who participate in MIPS receive a neutral or positive payment adjustment.

Comment: A few commenters suggested that the performance threshold remain at 30 points to allow clinicians to adjust to changes with program requirements. Some commenters recommended that CMS rework incentives for participation instead of increasing the performance threshold and the possibility of a negative payment adjustment. Several commenters recommended a smaller increase in the performance threshold for the 2022 MIPS payment year. One commenter suggested an increase from 30 points to 35 points because this increase would be consistent with the size of the proposed increase in the additional performance threshold for exceptional performance. One commenter stated a lower performance threshold of score of 35 points would reduce the magnitude of payment adjustments and the consequences of penalties or bonuses. One commenter

recommended that the performance threshold for the 2022 MIPS payment year should increase to 40 points and that the increase for the 2023 MIPS payment year should be delayed, but did not provide reasons for that recommendation.

Response: We thank the commenters for their suggestions. However, we do not believe that keeping the performance threshold at 30 points or increasing the performance threshold by 5 or 10 points would as effectively incentivize the delivery of high quality care for the 2022 MIPS payment year. We also do not believe it would provide as much of a gradual and incremental transition to the estimated performance threshold for the 2024 MIPS payment year, which we have estimated in the proposed rule at 74.01 points and still believe is an appropriate estimate after consideration of available data referenced in Table 59. We note that 74.01 points is the lowest of the two actual mean scores available and is close to our projections for mean final scores for the 2021 and 2022 MIPS payment years. We believe our proposal is an appropriate increase of 15 points from the performance threshold of 30 points for the 2021 MIPS payment year that would encourage an increased focus on the delivery of high-quality care to be successful in MIPS and receive a neutral or positive payment adjustment. In addition, we note that the gap from 30 points to approximately 75 points is much larger than any potential increase to the additional performance threshold. We also believe that delaying an increase for the 2023 MIPS payment year does not support our efforts to help eligible clinicians plan for future performance requirements under MIPS. We also believe that it is beneficial for planning purposes that we finalize the performance threshold for the 2023 MIPS payment year; however, we may revisit the performance threshold for the 2023 MIPS payment year in future rulemaking if we receive additional data that would cause us to reconsider our estimate of the performance threshold for the 2024 MIPS payment year.

Comment: One commenter stated the performance threshold should increase to 50 points for the 2022 MIPS payment year based on the increased mean score for the 2020 MIPS payment year which was mentioned in a webinar.

Response: We believe that an increase of 15 points from the performance threshold of 30 points for the 2021 MIPS payment year is an appropriate increase to incentivize high clinician performance. As discussed earlier, we believe a conservative approach is warranted for estimating the performance threshold for the 2024 MIPS payment year. Even though the actual mean score for the 2020 MIPS payment year is higher than we estimated, we do not believe that a higher actual mean score for the 2020 MIPS payment year warrants an increase to our proposed performance threshold for the 2022 MIPS payment year because we project the mean final scores for the 2021 MIPS payment year and the 2022 MIPS payment year to be lower than the mean final score for the 2020 MIPS payment. We also believe an increase to 50 points is too steep and that a performance threshold at 45 points for the 2022 MIPS payment year allows for a gradual and incremental transition to our estimated performance threshold for the 2024 MIPS payment year of 74.01 points.

Comment: Several commenters did not support our proposal of 45 points for the performance threshold for the 2022 MIPS payment year and stated that small and rural practices would be at a disadvantage to participate in MIPS compared to the larger groups. Some commenters recommended more bonus opportunities and developing a separate performance threshold for small and rural practices. One commenter stated that the increase in the performance threshold might lead to practice consolidation for small practices.

Response: We acknowledge the concerns of commenters regarding the potential impact on small practices. As discussed in a prior response, we have established special policies available for small practices to support their efforts to be successful in MIPS.

We also believe that different performance criteria for certain types of clinicians or practices may create more confusion and burden than a cohesive set of criteria; moreover, we are statutorily required to establish a single performance threshold for all MIPS eligible clinicians. We do not have data that would support the theory that increasing the performance threshold leads to the consolidation of small practices.

Comment: A few commenters did not support the increase in the performance threshold for the 2022 and 2023 MIPS payment years and stated it would have a negative impact on specialists. Some commenters noted this increase would make it difficult for pathologists, audiologists, physical therapists, ambulatory surgical center (ASC)-based and hospital-based MIPS eligible clinicians to meet the threshold due to a lack of quality measures for these practices. One commenter stated audiologists should be exempt from negative payment adjustments. One commenter expressed concern that quality measurement reporting requirements could result in lower scores for some specialties. One commenter recommended an analysis of the distribution of overall scores by specialty and sub-specialty is needed to help address disadvantages and possible upcoming negative adjustments.

Response: We appreciate the unique challenges faced by MIPS eligible clinicians that are in specialty practices, including pathologists, audiologists, physical therapists, and ASC-based and hospital-based MIPS clinicians. We believe that there are multiple pathways for clinicians, including specialty practices, to meet or exceed the performance threshold and be successful in MIPS and refer to the examples discussed at section III.K.3.e.(4) of this final rule. We also note that there are policies that adjust the quality performance category scores to account for the number of available quality measures, such as data validation process discussed in the CY 2017 Quality Payment Program final rule (81 FR 77290 through 77291) and the CY 2019 PFS final rule (83 FR 35950), and to assess if clinicians have fewer than 6 measures available and applicable for the quality performance category.

Comment: Several commenters expressed concerns with increasing the proposed thresholds while proposing significant changes to the cost and Promoting Interoperability performance categories believing that clinicians would not have enough time to adjust to the changes and this could result in lower scores.

Response: We acknowledge the concerns submitted by the commenters. We recognize that some requirements and scoring policies in the MIPS program have changed from year to year, including from the 2021 MIPS payment year to the 2022 MIPS payment year, but we believe the proposed performance threshold of 45 points for the 2022 MIPS payment year and 60 points for the 2023 MIPS payment year are appropriate increases that encourage increased participation and engagement in the MIPS program and that incentivize clinicians to transition to value-based care. We also note that we have modified the weight of the cost performance category in response to comments; specifically, we maintain the weight of the cost performance category at 15 percent for 2022 MIPS payment year to allow clinicians to become more familiar with the performance feedback process and allow us to continue to improve feedback reports. We do not

believe the policy changes to the Promoting Interoperability performance category referenced in section III.K.3.c.(4) of this final rule would require additional time for clinicians to adjust in order to avoid a negative payment adjustment. We also believe there are multiple pathways to meeting or exceeding a performance threshold of 45 points and refer readers to examples discussed at section III.K.3.e.(4) of this final rule.

After consideration of public comments, we are finalizing our proposal to set the performance threshold at 45 points for the 2022 MIPS payment year and at 60 points for the 2023 MIPS payment year. We are codifying the performance threshold for the 2022 MIPS payment year at § 414.1405(b)(7) and codifying the performance threshold for the 2023 MIPS payment year at § 414.1405(b)(8).

(3) Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under section 1848(q)(6)(C) of the Act. For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period described in section 1848(q)(6)(D)(i) of the Act. Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the $500 million of funding available for the year under section 1848(q)(6)(F)(iv) of the Act.

As we discussed in the CY 2020 PFS proposed rule (84 FR 40800 through 40803), we relied on the special rule under section 1848(q)(6)(D)(iii) of the Act to propose a performance threshold of 45 points for the 2022 MIPS payment year and to propose a performance threshold of 60 points for the 2023 MIPS payment year. The special rule under section 1848(q)(6)(D)(iii) of the Act also applies for purposes of establishing an additional performance threshold for a year, for the initial 5 years of MIPS. For the 2022 MIPS payment year and the 2023 MIPS payment year, we proposed again to rely on the discretion afforded by the special rule and to decouple the additional performance threshold from the performance threshold.

For illustrative purposes, we considered what the numerical values would be for the additional performance threshold under one of the methods described in section 1848(q)(6)(D)(ii) of the Act: The 25th percentile of the range of possible final scores above the performance threshold. With a proposed performance threshold of 45 points, the range of total possible points above the performance threshold is 45.01 to 100 points and the 25th percentile of that range is 58.75, which is just more than one-half of the possible 100 points in the MIPS final score. We stated that we do not believe it would be appropriate to lower the additional performance threshold to 58.75 points because it is below the mean and median final scores for each of the prior performance periods that are referenced in Table 51 of the CY 2020 PFS proposed rule (84 FR 40802). Similarly, with a proposed performance threshold for the 2023 MIPS payment year of 60 points, the range of possible points above the performance threshold is 60.01 to 100 points and the 25th percentile of that range is 69.99 points. We stated that we do not believe it would be appropriate to lower the additional performance threshold to 69.99 points because it is below or close to the mean and median final scores for each of the prior performance periods that are referenced in Table 51 of the CY 2020 PFS proposed rule (84 FR 40802).

We relied on the special rule under section 1848(q)(6)(D)(iii) of the Act and proposed at § 414.1405(d)(6) to set the additional performance threshold for the 2022 MIPS payment year at 80 points and proposed at § 414.1405(d)(7) to set the additional performance threshold for the 2023 MIPS payment year at 85 points. These values are higher than the 25th percentile of the range of the possible final scores above the proposed performance threshold for the 2022 and 2023 MIPS payment years.

We originally proposed 80 points for the additional performance threshold for the 2021 MIPS payment year in the CY 2019 PFS proposed rule (83 FR 35973) although we finalized 75 points in the CY 2019 PFS final rule (83 FR 59886). In the CY 2019 PFS final rule, we noted the impact that policy changes for the 2021 MIPS payment year could have on final scores as clinicians are becoming familiar with these changes and noted our belief that 75 points was appropriate for Year 3 of MIPS (83 FR 59883 through 59886). We also signaled our intent to increase the additional performance threshold in future rulemaking (83 FR 59886).

We stated that we believe that 80 points and 85 points are minimal and incremental increases over the additional performance threshold of 75 points for the 2021 MIPS payment year (84 FR 40803). We stated that we also believe it is appropriate to raise the bar on what is rewarded as exceptional performance for the 2022 and 2023 MIPS payment years and that increasing the additional performance threshold each year will encourage clinicians to increase their focus on value-based care and enhance the delivery of high quality care for Medicare beneficiaries (84 FR 40803).

An additional performance threshold of 80 points and 85 points would each require a MIPS eligible clinician to participate and perform well in multiple performance categories. Generally, under the performance category weights for the 2022 MIPS payment year proposed in the CY 2020 PFS proposed rule (84 FR 40795), a MIPS eligible clinician who is scored on all four performance categories could receive a maximum of 40 points towards the final score for the quality performance category or a maximum score of 65 points for participating in the quality performance category and Promoting Interoperability performance category, which are both below the proposed 80-point and 85-point additional performance thresholds. In addition, 80 points and 85 points are at a high enough level that MIPS eligible clinicians must submit data for the quality performance category to achieve this target. We stated that we believe setting the additional performance threshold at 80 points and 85 points could increase the incentive for exceptional performance while keeping the focus on quality performance (84 FR 40802).

We noted that under section 1848(q)(6)(F)(iv) of the Act, funding is available for additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act only through the 2024 MIPS payment year, which is the sixth year of the MIPS program (84 FR 40804). We stated that we believe it is appropriate to further incentivize clinicians whose performance meets or exceeds the additional performance threshold for the fourth and fifth years of the MIPS program (84 FR 40804). We recognized that setting a higher additional performance threshold may result in fewer clinicians receiving additional MIPS payment adjustments

(84 FR 40804). We also noted that a higher additional performance threshold could increase the maximum additional MIPS payment adjustment that a MIPS eligible clinician potentially receives if the funds available (up to $500 million for each year) are distributed over fewer clinicians that have final scores at or above the higher additional performance threshold (84 FR 40804).

We invited public comment on our proposals to set the additional performance threshold at 80 points for the 2022 MIPS payment year and at 85 points for the 2023 MIPS payment year. Alternatively, for the 2022 MIPS payment year, we considered whether the additional performance threshold should remain at 75 points or be set at a higher number, for example, 85 points, and also solicited comment on alternative numerical values for the additional performance threshold for the 2022 MIPS payment year. We referred readers to the RIA in the CY 2020 PFS proposed rule (84 FR 40911) for the estimated maximum payment adjustments when the additional performance threshold is set at 80 points and at 85 points, respectively, for the 2022 MIPS payment year.

Alternatively, for the 2023 MIPS payment year, we also considered whether the additional performance threshold should remain at 80 points as proposed for the 2022 MIPS payment year or whether a different numerical value should be adopted for the 2023 MIPS payment year, and also solicited comment on alternative numerical values for the additional performance threshold for the 2023 MIPS payment year. Additionally, in the event that we adopt different numerical values for the performance threshold in the final rule than proposed in the CY 2020 PFS proposed rule (84 FR 40800 through 40803), we solicited comment on whether we should adopt different numerical values for the additional performance threshold and how we should set those values. We also solicited comment on how the distribution of the additional MIPS payment adjustments across MIPS eligible clinicians may impact exceptional performance by clinicians participating in MIPS. For example, the distribution of the additional MIPS payment adjustments could result in a higher additional MIPS payment adjustment available to fewer clinicians or could result in a lower additional MIPS payment adjustment available to a larger number of clinicians. We also reminded readers that we anticipate the data will change over time and that the distribution of final scores will differ from one year to the next.

We received public comments on our proposals to set the additional performance threshold at 80 points for the 2022 MIPS payment year and at 85 points for the 2023 MIPS payment year. We also received public comments on alternative numerical values for the additional performance threshold for the 2022 MIPS payment year

We also received public comments on alternative numerical values for the additional performance threshold for the 2023 MIPS payment year, whether we should adopt different numerical values for the additional performance threshold and how we should set those values, and how the distribution of the additional MIPS payment adjustments across MIPS eligible clinicians may impact exceptional performance by clinicians participating in MIPS.

The following is a summary of the comments we received and our responses.

Comment: One commenter did not support the proposed additional performance threshold for the 2022 MIPS payment year and stated the additional performance threshold should be 85 points based on the increased mean score for 2020 MIPS payment year. Another commenter expressed concerns that clinicians who have invested in their practices to meet quality measure requirements and are performing at exceptional levels receive low payment adjustments of less than 2 percent for reaching the highest levels of MIPS scoring.

Response: We appreciate the investments made by clinicians to make improvements in their clinical practice and their efforts to transition to value-based care in the Medicare program. We note that a higher additional performance threshold could increase the maximum additional payment adjustment that a MIPS eligible clinician could potentially receive if the funds available (up to $500 million for the year) are distributed over fewer clinicians that score at or above the higher additional performance threshold. We appreciate the commenter's suggestion of 85 points for the additional performance threshold for the 2022 MIPS payment year.

We believe it is important to incentivize exceptional performance in MIPS and will increase the additional performance threshold from our proposal for the 2022 MIPS payment year of 80 points to 85 points. This adjustment would raise the bar on exceptional performance and provide an appropriate financial incentive for high performers.

As discussed in section VII.F.10 of the Regulatory Impact Analysis in this final rule, we estimate that the number of MIPS eligible clinicians receiving an additional payment adjustment with the additional performance threshold at 80 points and 85 points is 533,069 and 390,354 MIPS eligible clinicians, respectively. We found that increasing the additional performance threshold to 85 points rather than 80 points leads to a decrease in the number of MIPS eligible clinicians that would receive an additional payment adjustment by 142,715 clinicians. The estimated 390,354 MIPS eligible clinicians expected to receive the additional payment adjustment when the additional performance threshold is set at 85 points is about 44 percent of the MIPS eligible population compared to 61 percent of the MIPS eligible population when the additional performance threshold is set at 80 points. We also estimate that the maximum payment adjustment (for a MIPS eligible clinician with a final score of 100 points) would increase from 4.5 to 6.2 percent. However, this projection is only an estimate and may change based on the distribution of actual final scores for clinicians with final scores at or higher than the additional performance threshold and the associated Medicare payments. Given this analysis, we believe that increasing the additional performance threshold to 85 points for the 2022 MIPS payment year would provide an appropriate incentive for exceptional clinician performance.

We also note that the funding for the additional payment adjustment ends with the 2024 MIPS payment year and believe the additional performance threshold should be set at a number that encourages the transition to value-based care.

For the reasons discussed above, we believe 85 points is appropriate for the additional performance threshold for the 2022 MIPS payment year; therefore, we will finalize 85 points for the additional performance threshold for exceptional performance for both the 2022 and 2023 MIPS payment years.

Comment: A few commenters supported the proposed additional performance threshold for exceptional performance because they would reasonably raise the bar on what is rewarded as exceptional performance; ensure that clinicians continue to be held accountable for quality and cost; incentivize individuals and groups to continuously improve performance; and motivate health care providers to continually provide high quality health care for all patients. A few commenters supported our proposals believing that high-quality clinicians should receive

larger bonuses for meeting the additional performance threshold.

Response: We agree with commenters that increasing the additional performance threshold incentivizes individuals and groups to continuously improve performance and motivates health care providers to continually provide high quality health care for all patients. However, we also note that we received comments expressing concern that the MIPS payment adjustments would not provide for appropriate financial incentives for exceptional performers in MIPS.

We have considered the totality of the comments and more recent data discussed in the Regulatory Impact Analysis at section VII. of this final rule estimating the number of eligible clinicians receiving an additional payment adjustment and the potential increase in the additional payment adjustment with the additional performance threshold set at 80 points and 85 points and we believe it is appropriate to finalize a higher additional performance threshold for the 2022 MIPS payment year that further incentivizes continued care improvement by high performing clinicians that have invested in quality care and are exceptional performers in MIPS. Given this, we believe that an increase of 10 points from the additional performance threshold of 75 points for the 2021 MIPS payment year is a reasonable increase for the 2022 MIPS payment year and would provide an appropriate financial incentive for clinicians to deliver exceptional performance in MIPS.

Comment: Several commenters did not support the proposal to set the additional performance threshold at 80 points for the 2022 MIPS payment year. A few commenters stated it should remain at 75 points for the 2022 MIPS payment year and to 80 points for the 2023 MIPS payment year believing that clinicians should have more time to implement quality improvement projects. A few commenters stated the additional performance threshold should not exceed the 75-point threshold until more insight is gained by practice size. One commenter indicated that the proposed additional performance thresholds are too high and would have a negative impact on small practices. A few commenters did not support the proposals for the additional performance threshold and noted changes to the improvement activities and Promoting Interoperability performance categories would impede the ability to achieve high scores. One commenter recommended the additional performance threshold remain at 75 points for the 2022 MIPS payment year should the proposal to increase the percentage of clinicians who must perform an improvement activity for the group to receive credit for the improvement activities performance category be finalized.

Response: We believe that an increase for the additional performance threshold is appropriate for the 2022 MIPS payment year and the 2023 MIPS payment year to encourage high performance across all clinician practices and to support their transition to value-based care. We believe that keeping the additional performance threshold at 75 points for the 2022 MIPS payment year and increasing it to 80 points for the 2023 MIPS payment year does not appropriately raise the bar on exceptional performance. We also note that clinicians could still meet or exceed the performance threshold and receive a neutral or positive payment adjustment to be successful in the MIPS program. We recognize the unique challenges for eligible clinicians in small practices participating in MIPS and believe that special policies provide some relief for small practices seeking to perform well as referenced in earlier in this section of the final rule. We also believe that increasing the additional performance threshold aligns with policy changes for the 2022 MIPS payment year for the Promoting Interoperability performance category discussed at section III.K.3.c.(4) of this final rule and the changes to the group submission requirement for the improvement activities performance category discussed at section III.K.3.c.(3)(d) of this final rule that appropriately raise the bar on clinician performance for 2022 MIPS payment year and further support the transition toward value-based care.

Comment: A few commenters did not support the increase in the additional performance threshold for the 2022 and 2023 MIPS payment years believing it would have a negative impact on specialists. A few commenters stated achieving a score above 80 points would be difficult for some specialties and sub-specialties with a low number of quality measures, such as pathology. One commenter stated it is increasingly difficult for some specialties to meet some of the metrics, such as the Promoting Interoperability measures, and that exceptional performance should not imply a competition across specialties but be based on truly meaningful measures. One commenter stated an increase would make it difficult for hospital-based MIPS clinicians to meet the threshold due to a lack of quality measures. One commenter recommended an analysis of the distribution of overall scores by specialty and sub-specialty to address disadvantages and possible negative adjustments.

Response: We acknowledge that the number of quality measures available to clinicians can vary by specialty and practice, including pathology and for hospital-based clinicians. We believe our quality performance category scoring validation policy accounts for certain instances where clinicians have fewer than 6 measures available. We also believe these adjustments allow us to develop a fair comparison across different MIPS eligible clinicians and would not preclude clinicians in specialty practices from reaching the additional performance threshold. We agree that performance measurement should be based on meaningful measures and that our policies account for when measures are not available or applicable. We are also looking at ways to implement MVPs in a way to make the program more meaningful for clinicians.

Comment: Some commenters stated the additional performance threshold should increase based on performance results from the previous year rather than an arbitrary change.

Response: We disagree with the characterization that the additional performance threshold is set arbitrarily. In the proposed rule (84 FR 40803), for illustrative purposes, we considered what the numerical values would be for the additional performance threshold under one of the methods described in section 1848(q)(6)(D)(ii) of the Act: the 25th percentile of the range of possible final scores above the performance threshold. With a proposed performance threshold of 45 points, the range of total possible points above the performance threshold is 45.01 to 100 points and the 25th percentile of that range is 58.75, which is just more than one-half of the possible 100 points in the MIPS final score. Similarly, with a proposed performance threshold for the 2023 MIPS payment year of 60 points, the range of possible points above the performance threshold is 60.01 to 100 points and the 25th percentile of that range is 69.99 points. We still do not believe it would be appropriate to lower the additional performance threshold to 69.99 points or 58.75 points because these numbers are below or close to the mean and median final scores for each of the prior performance periods that are referenced in Table 59.

After consideration of public comments, we are not finalizing our proposal to set the additional performance threshold at 80 points for the 2022 MIPS payment year, and

instead, are finalizing the additional performance threshold at 85 points for the 2022 MIPS payment year. We are finalizing the additional performance threshold at 85 points for the 2023 MIPS payment year as proposed. We are codifying the additional performance threshold for the 2022 MIPS payment year and for the 2023 MIPS payment year at § 414.1405(d)(6).

(4) Example of Adjustment Factors

In the CY 2020 PFS proposed rule (84 FR 40804 through 40809),we provided a figure and several tables as illustrative examples of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our proposed policies for the 2022 MIPS payment year. We are updating the figure and tables based on our finalized policies in this final rule.

Figure 1 provides an example of how various final scores will be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on the policies for the 2022 MIPS payment year in this final rule. In Figure 1, the performance threshold is 45 points. The applicable percentage is 9 percent for the 2022 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 9 percent for the 2022 MIPS payment year) and results in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and results in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 11.25 points based on the performance threshold of 45 points for the 2022 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive the lowest negative applicable percentage (negative 9 percent for the 2022 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent. If the scaling factor is above 1.0, but less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be higher than 9 percent.

Only those MIPS eligible clinicians with a final score equal to 45 points (which is the performance threshold in this example) will receive a neutral MIPS payment adjustment. Because the performance threshold is 45 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor will be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points will be less than 9 percent.

Figure 1 illustrates an example of the slope of the line for the linear adjustments for the 2022 MIPS payment year, but it can change considerably as new information becomes available. In this example, the scaling factor for the MIPS payment adjustment factor is 0.1401. In this example, MIPS eligible clinicians with a final score equal to 100 will have a MIPS payment adjustment factor of 1.261 percent (9 percent × 0.1401). (Note that this is prior to adding the additional payment adjustment for exceptional performance, which is explained below.)

The additional performance threshold for the 2022 MIPS payment year is 85 points. An additional MIPS payment adjustment factor of 0.5 percent starts at the additional performance threshold and increases on a linear sliding scale up to 10 percent. This linear sliding scale line is also multiplied by a scaling factor that is greater than zero and less than or equal to 1.0. The scaling factor will be determined so that the estimated aggregate increase in payments associated with the application of the additional MIPS payment adjustment factors is equal to $500 million. In Figure 1, the example scaling factor for the additional MIPS payment adjustment factor is 0.499. Therefore, MIPS eligible clinicians with a final score of 100 will have an additional MIPS payment adjustment factor of 4.99 percent (10 percent × 0.499). The total adjustment for a MIPS eligible clinician with a final score equal to 100 would be 1 + 0.0126 + 0.0499 = 1.0625, for a total positive MIPS payment adjustment of 6.25 percent.

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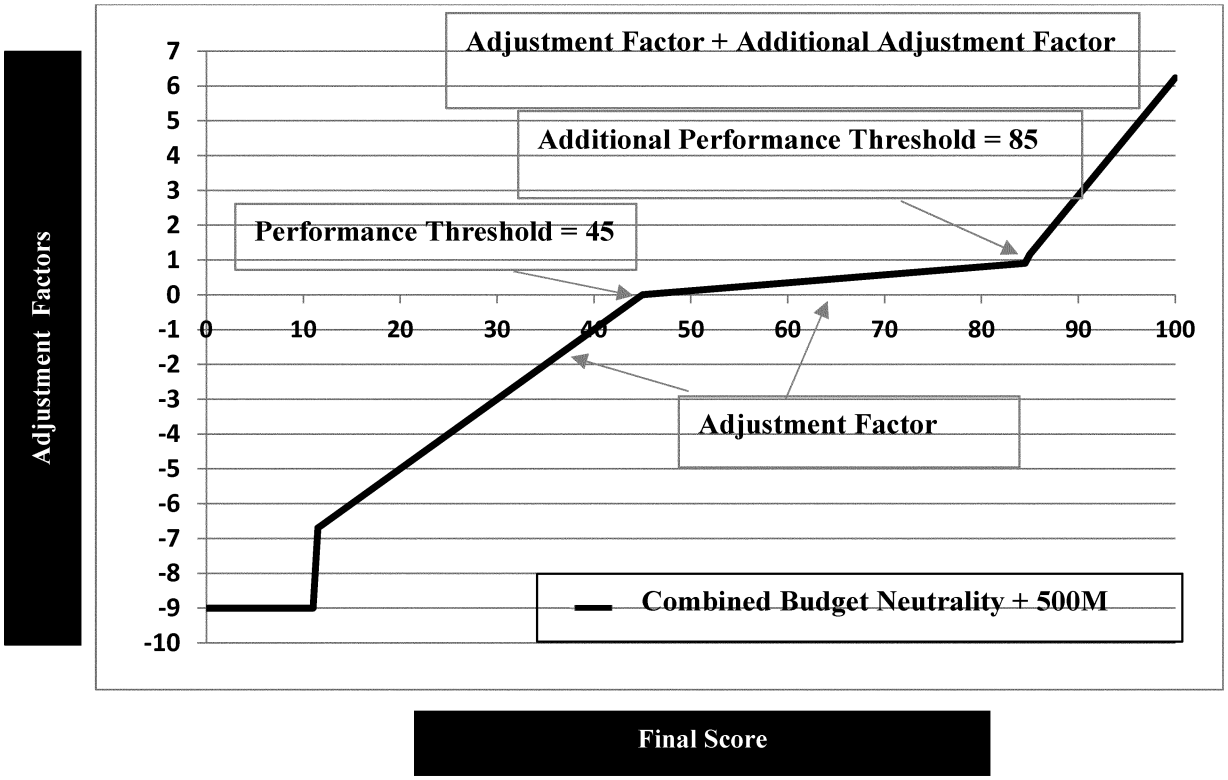
FIGURE 1: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2022 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. MIPS eligible clinicians with a final score of at least 85 points would also receive an additional adjustment factor for exceptional performance. The additional adjustment factor is also illustrative. The additional adjustment factor starts at 0.5 percent and cannot exceed 10 percent and is also multiplied by a scaling factor that is greater than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

The final MIPS payment adjustments will be determined by the distribution of final scores across MIPS eligible clinicians and the performance threshold. More MIPS eligible clinicians above the performance threshold means the scaling factors will decrease because more MIPS eligible clinicians receive a positive MIPS payment adjustment factor. More MIPS eligible clinicians below the performance threshold means the scaling factors will increase because more MIPS eligible clinicians will receive a negative MIPS payment adjustment factor and relatively fewer MIPS eligible clinicians will receive a positive MIPS payment adjustment factor.

Table 60 illustrates the changes in payment adjustments based on the final policies for the 2020 and 2021 MIPS payment years, and the policies for the 2022 and 2023 MIPS payment years discussed in this final rule, as well as the statutorily-required increase in the applicable percent as required by section 1848(q)(6)(B) of the Act.

TABLE 60: Illustration of Point System and Associated Adjustments Comparison between the 2020 MIPS Payment Year, the 2021 MIPS Payment Year, and the Policies for the 2022 MIPS Payment Year and the 2023 MIPS Payment Year

2020 MIPS payment year		2021 MIPS payment year		2022 MIPS payment year		2023 MIPS payment year	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-3.75	Negative 5%	0.0-7.5	Negative 7%	0.0-11.25	Negative 9%	0.0-15.0	Negative 9%
3.76-14.99	Negative MIPS payment adjustment greater than negative 5% and less than 0% on a linear sliding scale	7.51-29.99	Negative MIPS payment adjustment greater than negative 7% and less than 0% on a linear sliding scale	11.26-44.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	15.01-59.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
15.0	0% adjustment	30.0	0% adjustment	45.0	0% adjustment	60.0	0% adjustment
15.01-69.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	30.01-74.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	45.01-84.99.	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	60.01-84.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
70.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for final scores from 15.00 to 100.00. This sliding scale is multiplied by a	75.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for final scores from 30.00 to 100.00. This sliding scale is multiplied by a	85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final	85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges

2020 MIPS payment year		2021 MIPS payment year		2022 MIPS payment year		2023 MIPS payment year	
Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment
	scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.		scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.		scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.		from 0 to 9% for final scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionatel y distribute the available funds for exceptional performance

We have provided updated examples below with the policies finalized for the 2022 MIPS payment year to demonstrate scenarios in which MIPS eligible clinicians can achieve a final score above the proposed performance threshold of 45 points based on our final policies.

Example 1: MIPS Eligible Clinician in Small Practice Submits 5 Quality Measures and 1 Improvement Activity

In the example illustrated in Table 61, a MIPS eligible clinician in a small practice reporting individually exceeds the performance threshold by performing at the median level for 5 quality measures via Part B claims collection type and one medium-weight improvement activity. The practice does not submit data for the Promoting Interoperability performance category, but does submit a significant hardship exception application which is approved; therefore, the weight for the Promoting Interoperability performance

category is redistributed to the quality performance category under the proposed reweighting policies finalized in section III.K.3.d.(2)(b)(iii) of this proposed rule. We also assumed the small practice has a cost performance category percent score of 50 percent. Finally, we assumed a complex patient bonus of 3 points which represents the average HCC risk score for the beneficiaries seen by the MIPS eligible clinician, as well as the proportion of Medicare beneficiaries that are dual eligible. There are special scoring rules for the improvement activities performance category which affect MIPS eligible clinicians in a small practice.

- Six measure achievement points for each of the 5 quality measures submitted at the median level of performance. We refer readers to § 414.1380(b)(1)(i) for further discussion of the quality performance category scoring policy. Because the measures are submitted via Part B claims, they do not qualify for the end-to-end electronic reporting bonus, nor do the measures submitted qualify for the high-priority bonus. The small practice bonus of 6 measure bonus points apply because at least 1 measure was submitted. Because the MIPS eligible clinician does not meet full participation requirements, the MIPS eligible clinician does not qualify for improvement scoring. We refer readers to § 414.1380(b)(1)(vi) for the full participation requirements for improvement scoring. Therefore, the quality performance category is (30 measure achievement points + 6 measure bonus points)/60 total available measure points + zero improvement percent score which is 60 percent.
- The Promoting Interoperability performance category weight is redistributed to the quality performance category so that the quality performance category score is worth 70 percent of the final score. We refer readers to section III.K.3.d.(2)(b)(iii) of this final rule for a discussion of this policy.
- MIPS eligible clinicians in small practices qualify for special scoring for improvement activities so a medium weighted activity is worth 20 points out of a total 40 possible points for the improvement activities performance category. We refer readers to § 414.1380(b)(3) for further detail on scoring policies for small practices for the improvement activities performance category.
- This MIPS eligible clinician exceeds the performance threshold of 45 points (but does not exceed the additional performance threshold). This score is summarized in Table 61.

TABLE 61: Scoring Example 1, MIPS Eligible Clinician in a Small Practice

[A] Performance Category	[B] Performance Score	[C] Category Weight	[D] Earned Points ([B]*[C]*100)
Quality	60%	70%	42
Cost	50%	15%	7.5
Improvement Activities	20 out of 40 points - 50%	15%	7.5
Promoting Interoperability	N/A	0% (redistributed to quality)	0
Subtotal (Before Bonuses)			57
Complex Patient Bonus			3
Final Score (not to exceed 100)			**60**

Example 2: Group Submission Not in a Small Practice

In the example illustrated in Table 62, a MIPS eligible clinician in a medium size practice participating in MIPS as a group receives performance category scores of 80 percent for the quality performance category, 60 percent for the cost performance category, 90 percent for the Promoting Interoperability performance category, and 100 percent for improvement activities performance category. There are many paths for a practice to receive an 80 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated at this amount. Again, for simplicity, we assume a complex patient bonus of 3 points. The final score is calculated to be 85.5 points, and both the performance threshold of 45 points and the additional performance threshold of 85 points are exceeded. In this example, the group practice exceeds the additional performance threshold and will receive the additional MIPS payment adjustment.

TABLE 62: Scoring Example 2, MIPS Eligible Clinician in a Medium Practice

[A] Performance Category	[B] Performance Score	[C] Category Weight	[D] Earned Points ([B]*[C]*100)
Quality	80%	45%	36
Cost	60%	15%	9
Improvement Activities	40 out of 40 points - 100%	15%	15
Promoting Interoperability	90%	25%	22.5
Subtotal (Before Bonuses)			82.5
Complex Patient Bonus			3
Final Score (not to exceed 100)			**85.5**

Example 3: Non-Patient Facing MIPS Eligible Clinician

In the example illustrated in Table 63, an individual MIPS eligible clinician that is non-patient facing and not in a small practice receives performance category scores of 50 percent for the quality performance category, 50 percent for the cost performance category, and 50 percent for 1 medium-weighted improvement activity. Again, there are many paths for a practice to receive a 50 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated. Because the MIPS eligible clinician is non-patient facing, they qualify for special scoring for improvement activities and receive 20 points (out of 40 possible points) for the medium weighted activity. Also, this individual did not submit Promoting Interoperability measures and qualifies for the automatic redistribution of the Promoting Interoperability performance category weight to the quality performance category. Again, for simplicity, we assume a complex patient bonus of 3 points.

In this example, the final score is 53 points and the performance threshold of 45 points is exceeded while the additional performance threshold of 85 points is not.

TABLE 63: Scoring Example 3, Non-Patient Facing MIPS Eligible Clinician

[A] Performance Category	[B] Performance Score	[C] Category Weight	[D] Earned Points ([B]*[C]*100)
Quality	50%	70%	35
Cost	50%	15%	7.5
Improvement Activities	20 out of 40 points for 1 medium weight activity - 50%	15%	7.5
Promoting Interoperability	0%	0% (redistributed to quality)	0
Subtotal (Before Bonuses)			50
Complex Patient Bonus			3
Final Score (not to exceed 100)			**53**

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We note that these examples are not intended to be exhaustive of the types of participants in MIPS nor the opportunities for reaching and exceeding the performance threshold.

f. Targeted Review and Data Validation and Auditing

For previous discussions of our policies for targeted review, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358).

In the CY 2020 PFS proposed rule (84 FR 40809 through 40810), we proposed to: (1) Identify who is eligible to request a targeted review; (2) revise the timeline for submitting a targeted review request; (3) add criteria for denial of a targeted review request; (4) update requirements for requesting additional information; (5) state who will be notified of targeted review decisions and require retention of documentation submitted; and (6) codify the policy on scoring recalculations. These proposals are discussed in more detail in this section of the final rule.

(1) Targeted Review

(a) Who Is Eligible To Request Targeted Review

In the CY 2017 Quality Payment Program final rule, we established at § 414.1385(a) that MIPS eligible clinicians and groups may submit a targeted review request and that these submissions could be with or without the assistance of a third party intermediary (81 FR 77353). As we stated in the CY 2020 PFS proposed rule (84 FR 40809), in our efforts to minimize burden on MIPS eligible

clinicians and groups, we believe it is important to allow designated support staff and third party intermediaries to submit targeted review requests on their behalf. To expressly acknowledge the role of designated support staff and third party intermediaries in the targeted review process, we proposed to revise § 414.1385(a)(1) to state that a MIPS eligible clinician or group (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review. MIPS eligible clinicians and groups (including their designated support staff) can request a targeted review by logging into the Quality Payment Program website at *qpp.cms.gov,* and after reviewing their performance feedback for the relevant performance period and MIPS payment year, they can submit a request for targeted review. An authorized third party intermediary as defined at § 414.1305, such as a qualified registry, health IT vendor, or QCDR, that does not have access to their clients' performance feedback still would be able to request a targeted review on behalf of their clients. Third party intermediaries do not have access to the performance feedback of MIPS eligible clinicians and groups; therefore, we will share an URL link to the Targeted Review Request Form with these designated entities. In the CY 2017 Quality Payment Program final rule, we established at § 414.1385(a)(2) that we will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted (81 FR 77353). We proposed to redesignate this provision as § 414.1385(a)(4).

The following is a summary of the comments we received on the proposals regarding who is eligible to request targeted review and our responses.

Comment: Several commenters supported the proposal for a MIPS eligible clinician, group (including their designated support staff), or a third-party intermediary to have the ability to submit a request for a targeted review because of the belief that the policy takes into account resources of small and mid-sized groups and reduces administrative burden on physician practices. Commenters also supported the proposal because they believed third party intermediaries may potentially have more of a working knowledge of measure scoring and streamlining review requests, which may expedite review and approval of a targeted review request.

Response: We agree that the proposal allowing for a MIPS eligible clinician, group (including their designated support staff), or a third-party intermediary to submit a request for a targeted review takes into account the resources of small and mid-sized groups. We recognize the benefit of allowing those working with clinicians, such as support staff and third party intermediaries, to submit a targeted review request therefore reducing burden for MIPS eligible clinicians and groups and improving the efficiency of the targeted review process.

After consideration of the public comments received, we are finalizing our proposal, as proposed, to revise § 414.1385(a)(1) to state that a MIPS eligible clinician or group (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review. We received no comments on our proposal to redesignate as § 414.1385(a)(4) the provision previously designated as § 414.1385(a)(2), which states that we will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted and are finalizing the redesignation as proposed.

(b) Timeline for Targeted Review Requests

In the CY 2017 Quality Payment Program final rule (81 FR 77358), we finalized at § 414.1385(a)(1) that MIPS eligible clinicians and groups have a 60-day period to submit a request for targeted review, which begins on the day we make available the MIPS payment adjustment factor, and if applicable the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors), for the MIPS payment year and ends on September 30 of the year prior to the MIPS payment year or a later date specified by CMS. During the first year of targeted review for MIPS, we allowed MIPS eligible clinicians and groups 90 days, with an additional 14-day extension, to submit a targeted review request. In response to user feedback, in December 2018, we made available revised performance feedback to MIPS eligible clinicians and groups who had filed a targeted review request. As we stated in the CY 2020 PFS proposed rule (84 FR 40809), we believe it is important to ensure MIPS eligible clinicians and groups have an opportunity to review their revised performance feedback prior to the application of the MIPS payment adjustment factors. We stated that we anticipate that by limiting the targeted review period to 60 days, we would be able to make available the revised performance feedback during October of the year prior to the MIPS payment year, which would be approximately 2 months earlier than what we were able to do for the first year of targeted review. Therefore, we proposed to revise § 414.1385(a)(2) to state that all requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors for the MIPS payment year, and to state that the targeted review request submission period may be extended as specified by CMS. We proposed this change would apply beginning with the 2019 performance period.

The following is a summary of the comments we received on the proposals regarding the timeline for targeted review requests and our responses.

Comment: A few commenters supported the proposal to change the timeline for submitting a targeted review request to 60 days because of their belief that it is a reasonable amount of time, may allow for a consistent period of time to submit questions, and may give CMS flexibility if feedback reports are delayed.

Response: We agree that the proposal to limit the period for submitting a targeted review request to 60 days is reasonable and adequate.

Comment: A few commenters expressed concern with the proposal to change the timeline for submitting a targeted review request to 60 days because they indicated it may limit an eligible clinician's time to review their performance feedback report, particularly eligible clinicians who may have been assessed inaccurately. One commenter expressed concern and recommended increased transparency related to the timeline for targeted review requests for eligible clinicians, groups (and their support staff), and third-party intermediaries. One commenter expressed concern over the proposal and recommended adding a targeted review category specific to vendor issues that would apply to eligible clinicians who experienced a data submission issue caused by a third-party intermediary. One commenter expressed concern and recommended adding an exception to the targeted review timeline for eligible clinicians and groups who have received an automatic extreme and uncontrollable circumstances exception.

Response: We believe that a 60-day submission period for targeted review requests is sufficient, as we have seen that eligible clinicians or groups who have identified errors typically submit targeted review requests at the start of the targeted review request submission

period, with a significant decrease in targeted review requests towards the end of the period. The release of the MIPS payment adjustment factors and performance feedback reports at the start of the targeted review request submission period would allow ample time for eligible clinicians, groups (and their support staff), and third-party intermediaries to properly submit an informed targeted review request. We believe that our proposal to limit the targeted review request submission period to 60 days would provide transparency related to the timeline for targeted review requests. We appreciate the recommendation of adding a targeted review category specific to third party intermediary issues. However, we continue to believe that MIPS eligible clinicians and groups are ultimately responsible for the data that is submitted by their third party intermediary and should hold their third party intermediary accountable for accurate reporting. In addition, in section III.K.3.d.(2)(b)(ii)(A) of this final rule, we are establishing a policy to reweight the performance categories for a MIPS eligible clinician who we determine has data that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents, which could address some of the commenter's concerns about vendor issues. We appreciate the feedback concerning extreme and uncontrollable circumstances. We will continue to reweight the performance categories for MIPS eligible clinicians who qualify for the automatic extreme and uncontrollable circumstances policy, without the submission of a targeted review request, and we do not believe an exception to the targeted review timeline is warranted.

Comment: One commenter recommended aligning the MIPS and APM timelines in order for MIPS targeted reviews to be completed prior to the release of the APM results because they believe it may allow for corrections to reflect the final ACO Quality Scores and Shared Savings rates.

Response: We currently send unofficial reports to eligible clinicians that do reflect a change in ACOs, as a result of a targeted review or other changes. Due to ACO scoring update parameters, unfortunately, the APM and MIPS programmatic timing of report releases and the end of targeted review cannot be aligned.

After consideration of the public comments received, we are finalizing our proposal, as proposed, to revise § 414.1385(a)(2) to state that all requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day we make available the MIPS payment adjustment factors for the MIPS payment year, and to state that the targeted review request submission period may be extended as specified by CMS. We are finalizing our proposal, as proposed, that this change will apply beginning with the 2019 performance period.

(c) Denial of Targeted Review Requests

Each targeted review request is carefully reviewed based upon the information provided at the time the request is submitted. During the first year of targeted review, CMS received many targeted review requests that were duplicative. We continue to seek opportunities to limit burden and improve the efficiency of our processes. Therefore, we proposed (84 FR 40810) to revise § 414.1385(a)(3) to state that a request for a targeted review may be denied if: The request is duplicative of another request for targeted review; the request is not submitted during the targeted review request submission period; or the request is outside of the scope of targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician or group for a year. We stated that notification would be provided to the individual or entity that submitted the targeted review request as follows:

- If the targeted review request is denied; in this case, there will be no change to the MIPS final score or associated MIPS payment adjustment factors for the MIPS eligible clinician or group.
- If the targeted review request is approved; in this case, the MIPS final score and associated MIPS payment adjustment factors may be revised, if applicable, for the MIPS eligible clinician or group.

The following is a summary of the comments we received on the proposals regarding the denial of targeted review requests and our responses.

Comment: One commenter suggested that CMS should not deny both requests for targeted review if duplicate requests are received because they indicated it may be punitive to eligible clinicians who are attempting to fix issues in their performance feedback, MIPS final scores, and/or payment adjustment determination.

Response: We agree and will only deny the duplicate request for a targeted review, not the initial request. If there is a change to an eligible clinician or groups performance feedback, MIPS final scores, and/or payment adjustment determination, that targeted review would not be considered a duplicate but viewed as additional information around that initial targeted review request.

Comment: One commenter expressed concern with the proposal to add criteria for denial of a targeted review request and recommended instituting a process for reviewing targeted review requests that have been denied because of their belief that such a review process may promote integrity within MIPS.

Response: We believe that establishing the reasons for which a targeted review request may be denied creates transparency with the targeted review process and MIPS, and improves the efficiency of our processes. However, we believe that further review of requests that have been denied may be counterproductive to the efficiency of our processes. We note that section 1848(q)(13)(A) of the Act describes the review process as ''targeted'' and ''informal,'' and on that basis, we do not believe that further review of requests that have been denied is warranted (81 FR 77353).

After consideration of the public comments received, we are finalizing our proposal, as proposed, to revise § 414.1385(a)(3) to state that a request for a targeted review may be denied if: The request is duplicative of another request for targeted review; the request is not submitted during the targeted review request submission period; or the request is outside of the scope of targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician or group for a year.

(d) Request for Additional Information

In the CY 2017 Quality Payment Program final rule (81 FR 77358), we finalized at § 414.1385(a)(3) that the MIPS eligible clinician or group may include additional information in support of their request for targeted review at the time the request is submitted, and if CMS requests additional information from the MIPS eligible clinician or group, it must be provided and received by CMS within 30 days of the request, and that non-responsiveness to the request for additional information may result in the closure of the targeted review request, although the MIPS eligible clinician or group may submit another request for targeted review before the deadline. Supporting documentation is a critical component of evaluating and processing a targeted review request. We may need to request supporting documentation, as

each targeted review request is reviewed individually and by category. Therefore, we proposed (84 FR 40810) to add § 414.1385(a)(5) to state that a request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician or group that is the subject of a request for a targeted review, it must be provided and received by CMS within 30 days of CMS' request. Non-responsiveness to CMS' request for additional information may result in a final decision based on the information available, although another request for a targeted review may be submitted before the end of the targeted review request submission period. Documentation can include, but is not limited to:

- Supporting extracts from the MIPS eligible clinician or group's EHR.
- Copies of performance data provided to a third party intermediary by the MIPS eligible clinician or group.
- Copies of performance data submitted to CMS.
- Quality Payment Program Service Center ticket numbers.
- Signed contracts or agreements between a MIPS eligible clinician/group and a third party intermediary.

The following is a summary of the comments we received on the proposals regarding requests for additional information and our responses.

Comment: Commenters expressed concern regarding the proposal to update requirements for requesting additional information as part of targeted review, specifically recommending a one-time extension of the 30-day timeframe for eligible clinicians and groups to submit additional information. A commenter shared their belief that quality data held by a third party intermediary may not be accessible within the 30-day timeframe.

Response: We agree that in certain circumstances, an extension to the 30-day timeframe may be warranted. We will consider granting an extension on a case-by-case basis, but the request for an extension should be submitted before the end of the 30-day period.

After consideration of the public comments received, we are finalizing our proposal, with modification, to add § 414.1385(a)(5) to state that a request for a targeted review may include additional information in support of the request at the time it is submitted. If we request additional information from the MIPS eligible clinician or group that is the subject of a request for a targeted review, it must be provided and received by CMS within 30 days of CMS' request. Non-responsiveness to our request for additional information may result in a final decision based on the information available, although another non-duplicative request for a targeted review may be submitted before the end of the targeted review request submission period. The modification to the regulation text is intended to clarify that if another request for targeted review is submitted, it cannot be duplicative of a prior request.

(e) Notification of Targeted Review Decisions

In the CY 2017 Quality Payment Program final rule (81 FR 77358), we finalized at § 414.1385(a)(4) that decisions based on the targeted review are final, and there is no further review or appeal. We proposed (84 FR 40810) to renumber this paragraph as § 414.1385(a)(7) and to add text to § 414.1385(a)(7) to state that CMS will notify the individual or entity that submitted the request for a targeted review of the final decision. To align with policies finalized at § 414.1400(g) regarding the auditing of entities submitting MIPS data, we also proposed to add § 414.1385(a)(8) to state that documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period.

The following is a summary of the comments we received on the proposals regarding the notification of targeted review decisions and our responses.

Comment: One commenter did not support our existing policy that targeted review decisions are final and no appeal or further review may be requested. They recommended that the targeted review process should expand beyond a one-level process, allow for live technical assistance, and include detailed feedback on the results, particularly on why eligible clinicians or groups may have a particular score. They noted that these changes to the process may help identify areas for improvement and may decrease errors over time.

Response: As mentioned in a prior response, we believe that further review of targeted review decisions may be counterproductive to the efficiency of our processes. We again note that section 1848(q)(13)(A) of the Act describes the review process as ''targeted'' and ''informal,'' and on that basis, we do not believe that a second level of review process is warranted. At this time, we cannot operationalize live technical assistance on performance feedback or scores due to time required for researching individual data, program limitations and the volume of targeted review requests received. We currently hold webinars for stakeholder engagement and that may highlight areas of improvement and possibly decrease errors over time.

Comment: One commenter supported the proposal to require retention of documentation submitted for targeted review for 6 years because they believed that it may ensure accuracy of targeted reviews.

Response: We agree that the proposal to require retention of documentation submitted for targeted review for 6 years is beneficial and maintains integrity within the targeted review process.

After consideration of the public comments received, we are finalizing our proposal, as proposed, to add § 414.1385(a)(8) to state that documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period. We did not receive comments on our proposal to renumber as § 414.1385(a)(7), the provision at § 414.1385(a)(4), which states that decisions based on the targeted review are final, and there is no further review or appeal and we are finalizing this renumbering as proposed.

(f) Scoring Recalculations

In the CY 2017 Quality Payment Program final rule (81 FR 77353), we stated that if a request for targeted review is approved, the outcome of such review may vary. We stated, for example, we may determine that the clinician should have been excluded from MIPS, re-distribute the weights of certain performance categories within the final score (for example, if a performance category should have been weighted at zero), or recalculate a performance category score in accordance with the scoring methodology for the affected category, if technically feasible (81 FR 77353). Therefore, we proposed (84 FR 40810) to add § 414.1385(a)(6) to state that if a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician or group with regard to the measures, activities, performance categories, and final score, as well as the MIPS payment adjustment factors.

The following is a summary of the comments we received on the proposals regarding scoring recalculations and our responses.

Comment: A commenter recommended that once a targeted review is approved and if the score of an eligible clinician or group with regard to measures, activities, performance categories, and final score, as well as payment adjustment is

changed, a written alert should be issued to the eligible clinician or group that provides additional details explaining the change.

Response: After we notify the submitter of a targeted review request of our final decision, the MIPS eligible clinician or group that is the subject of the request should review their performance feedback regarding updated performance category or final score results. We will consider an automated notification of performance feedback changes with basic explanation in future years.

We are finalizing our proposal, as proposed, to add § 414.1385(a)(6) to state that if a request for a targeted review is approved, we may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician or group with regard to the measures, activities, performance categories, and final score, as well as the MIPS payment adjustment factors.

(2) Data Validation and Auditing

For previous discussions of our policies for data validation and auditing at § 414.1390, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77358 through 77362). Among other requirements, § 414.1390(b) establishes that all MIPS eligible clinicians and groups that submit data and information to CMS for purposes of MIPS must certify to the best of their knowledge that the data submitted is true, accurate and complete. MIPS data that are inaccurate, incomplete, unusable or otherwise compromised can result in improper payment. Despite these existing obligations, we have received inquiries regarding perceived opportunities to selectively submit data that are unrepresentative of the MIPS performance of the clinician or group. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period, commonly referred to as ''cherry-picking,'' results in data submissions that are not true, accurate or complete. A clinician or group cannot certify that data submitted to CMS are true, accurate and complete to the best of its knowledge if they know the data submitted is not representative of the clinician's or group's overall performance for a performance period. Accordingly, a clinician or group that submits a certification under § 414.1390(b) in connection with the submission of data they know is cherry-picked has submitted a false certification in violation of existing regulatory requirements. If we believe cherry-picking of data may be occurring, we may subject the MIPS eligible clinician or group to auditing in accordance with § 414.1390(a) and in the case of improper payment a reopening and revision of the MIPS payment adjustment in accordance with § 414.1390(c).

The following is a summary of the comments we received on data validation and auditing and our responses.

Comment: One commenter recommended that CMS publish aggregate findings of previous audits with regard to suspected instances of cherry-picked data.

Response: We appreciate the feedback and will consider publishing the aggregate findings of previous audits surrounding cherry-picked data in connection with future educational efforts.

Comment: A commenter requested clarification that if a clinician who submits data on a single patient in order to receive the minimum point threshold for a quality measure, CMS would not conclude the clinician was cherry-picking data.

Response: We are clarifying that existing policy takes into consideration that MIPS eligible clinicians may submit data in accordance with CMS data submission requirements on a single measure. We believe that even in the context of submitting data on a single patient in order to receive the minimum point threshold, the patient selected should be representative. In other instances where cherry-picking is suspected, we will determine whether a clinician is using selection criteria inappropriately to create an unrepresentative submission for MIPS performance on a case-by-case basis. For additional policies on MIPS final score methodologies, we refer readers to section III.K.3.d of this final rule.

Comment: A few commenters supported the statement that if CMS believes the cherry-picking of data may be occurring, a MIPS eligible clinicians or group may be audited and in the case of improper payment, MIPS payment adjustment may be reopened and revised.

Response: We appreciate the commenters support and agree that if the cherry-picking of data is suspected that a MIPS eligible clinician or group may be audited and in the case of improper payment, a MIPS payment adjustment may be reopened and revised.

g. Third Party Intermediaries

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), and the CY 2019 PFS final rule (83 FR 59894 through 59910) for our previously established policies regarding third party intermediaries.

In the CY 2020 PFS proposed rule (84 FR 40811 through 40821), we proposed to make several changes. We proposed to establish new requirements for MIPS performance categories that must be supported by QCDRs, qualified registries, and Health IT vendors. We proposed to modify the criteria for approval as a third party intermediary, and establish new requirements to promote continuity of service to clinicians and groups that use third party intermediaries for their MIPS submissions. With respect to QCDRs, we also proposed requirements to: Engage in activities that will foster improvement in the quality of care; and enhance performance feedback requirements. These QCDR proposals would also affect the self-nomination process. We also proposed to update considerations for QCDR measures. With respect to qualified registries, we also proposed to require enhanced performance feedback requirements. Finally, we clarified the remedial action and termination provisions applicable to all third party intermediaries.

Because we believe that third party intermediaries, such as QCDRs, represent a useful path to fulfilling MIPS requirements while reducing the reporting burden for clinicians, we believe the policies discussed in this section justify the Collection of Information and Regulatory Impact Analysis burden estimates discussed in sections VI. and VII. of this final rule, respectively, for additional information on the costs and benefits.

(1) Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

We refer readers to § 414.1400(a)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088) for our current policy regarding the types of MIPS data third-party intermediaries may submit. In summary, the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. Through education and outreach, we have become aware of stakeholders' desires to have a more cohesive participation experience across

all performance categories under MIPS. Specifically, we have heard of instances where clinicians would like to use their QCDR or qualified registry for reporting the improvement activities and promoting interoperability performance categories, but their particular third party intermediary does not support all categories, only quality. Based on this feedback and additional data regarding QCDRs and qualified registries respectively, which are discussed further below, we believe it is reasonable to strengthen our policies at § 414.1400(a)(2), and require QCDRs and qualified registries to support three performance categories: Quality; improvement activities; and Promoting Interoperability. Accordingly, we proposed to amend § 414.1400(a)(2) to state that beginning with the 2023 MIPS payment year (2021 performance period) and for all future years, for the MIPS performance categories identified in the regulation, QCDRs and qualified registries must be able to submit data for each category, and Health IT vendors must be able to submit data for at least one category (84 FR 40811). We solicited feedback on the benefits and burdens of this proposal, including whether the requirement to support all three identified categories of MIPS performance data should extend to health IT vendors.

As discussed in the CY 2020 PFS proposed rule, however, we recognized the need to create an exception such that third party intermediaries would not be required to submit data for the Promoting Interoperability performance category if it only represents MIPS eligible clinicians, groups and virtual groups that are eligible for reweighting under the Promoting Interoperability performance category. For example, as discussed in the CY 2019 PFS final rule (83 FR 59819 through 59820), physical therapists generally are eligible for reweighting of the Promoting Interoperability performance category to zero percent of the final score; therefore, under this exception, a QCDR or qualified registry that represents only physical therapists that reweighted the Promoting Interoperability performance category to zero percent of the final score, would not be required to support the Promoting Interoperability performance category. Therefore, we proposed to revise § 414.1400(a)(2)(iii) to state that for the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) or (5) or § 414.1380(c)(2)(i)(C)(1)–(7) or § 414.1380(c)(2)(i)(C)(*9*) (84 FR 40811). We refer readers to section III.K.3.c.(4) of this final rule for additional information on the clinician types that are eligible for reweighting the Promoting Interoperability performance category. We noted that we anticipate using the self-nomination vetting process to assess whether the QCDR or qualified registry is subject to our requirement to support reporting the Promoting Interoperability performance category. We solicited comments on this proposal, including the scope of the exception from the Promoting Interoperability reporting requirement for certain types of QCDRs and qualified registries. Specifically, we solicited comment on whether we should more narrowly tailor, or conversely broaden, the proposed exceptions for when QCDRS and qualified registries must support the Promoting Interoperability performance category.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed their agreement with the proposal to require QCDRs and qualified registries to support the reporting of data for the quality, Promoting Interoperability, and the improvement activities performance categories, as well as the exemption for third party intermediaries who only serve specialties that are exempt from the Promoting Interoperability performance category.

Response: We thank commenters for their support. We direct readers to the QCDR and qualified registry sections below III.K.3.g.(3) and III.K.3.g.(4) for detailed comment and responses regarding these proposals.

Comment: Several commenters expressed their belief that the scope of proposals in the proposed rule negatively impacts QCDRs and Qualified Registries in general to the point where some third-party intermediaries may end their participation in MIPS. They believe the proposals shift costs and burden of administering the MIPS program onto physicians via their specialty societies that create measures and have QCDRs and require QCDRs to perform services that were not part of the original quality program.

Response: The intent of our proposals is to ensure that the QCDRs and qualified registries that are approved in the program are of the highest quality, and can be used as reliable resources to support quality reporting on behalf of eligible clinicians and groups. We understand that an increase in requirements may cause increased burden to QCDRs and qualified registries, but believe that high-performing third party intermediaries are capable of meeting these requirements. Through the legacy PQRS program and the first few years of MIPS, we have witnessed instances of third party intermediaries, specifically QCDRs and qualified registries leaving the program mid-performance period, creating additional burden to the clinicians who were depending on them for reporting purposes. There have also been instances where QCDRs and qualified registries were unable to support measures, after indicating they could, or having errors related to data submissions. We believe these type of issues also contribute to clinician burden and are addressed through our additional policies as described in this section of the final rule. We refer readers to the Collection of Information and Regulatory Impact Analysis burden estimates discussed in sections VI. and VII. of this final rule, respectively, for additional information on the costs and benefits related to our finalized policies.

Comment: Many commenters opposed the proposal to require QCDRs to support the reporting of data for the quality, Promoting Interoperability, and improvement activities performance categories, specifically citing the requirements to audit and validate Promoting Interoperability data and improvement activities. Several of the commenters stated their opinion that this would represent a significant additional burden, in part due to what they believe to be large increase in the data that would need to be collected without adding any distinct benefit to MIPS eligible clinicians and groups who already have other methods available for reporting MIPS data, and that some QCDRs may incur additional costs from EHR vendors who may charge fees for providing additional necessary reports. One commenter also cited their belief that the QCDRs/registries currently supporting the Promoting Interoperability performance category use a health information exchange (*https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/what-hie*) and that vendors operating in areas that do not have a health information exchange would not be able to report on these measures. A few commenters cited their opinion that if the proposal is finalized, the resulting burden may result in many QCDRs electing to reevaluate their decisions to

seek approval to submit MIPS data. A few commenters also stated their opinion that if the proposal is finalized, they would need CMS to provide additional guidance and descriptions of what data would be necessary to validate that an individual MIPS eligible clinician or group could appropriately attest to a specific improvement activity.

Response: We thank the commenters for their suggestions. However, in this case, a majority of existing qualified registries and QCDRs already support all three performance categories which require data submission. We do acknowledge that a small minority of qualified registries and QCDRs may not be able to comply with this requirement, and as a result may elect not to continue in the Quality Payment Program. While we do not yet have data to share for how clinicians participated in 2019 (year 3), we do want to indicate that we have observed from 2017 (year 1) to 2018 (year 2) approximately 24 percent increasing to 36 percent of clinicians have used their QCDR/qualified registry for submitting for all 3 performance categories. We believe when this policy becomes finalized, more MIPS eligible clinicians may want to use this method as a burden reduction on data submission. We also believe the added benefit this policy provides to clinicians who want to use a qualified registry or QCDR to support data submission for the three performance categories outweighs the small number of qualified registries and QCDRs that are not able to comply, and that is why we are taking this step to finalize this policy.

As described in the CY 2017 Quality Payment Program final rule (81 FR 77366 and 81 FR 77384), QCDRs and qualified registries must audit a subset of data prior to submission for all performance categories that the QCDR or qualified registry is submitting data on, that is, quality, improvement activities, and promoting interoperability (previously known as advancing care information). We understand that this policy will require the minority of existing QCDRs and qualified registries who do not support all three performance categories to take on additional efforts and resources to support the remaining performance categories in order to retain their approval. Although some EHR vendors may charge for reports, we believe that the costs will be minimal because CEHRT includes the capability to calculate the Promoting Interoperability measures and the reports that must be generated. In addition, the use of health information exchanges (*https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/what-hie*) is an option for transmitting data; their use is not a requirement.

However, we believe that this policy allows for QCDRs and qualified registries to become one-stop-shops for reporting, and will thereby reduce reporting burden for eligible clinicians and groups. Under our current data validation processes, as described in the CY 2017 Quality Payment Program final rule (81 FR 77368 through 77369) and (81 FR 77384 through 77385), QCDRs and qualified registries are required to provide information on their sampling methodology. For example, it is encouraged that 3 percent of TIN/NPIs submitted be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of 5 patients (with a maximum sample of 50 patients). We would expect that this review of patient medical records would be done to validate that the pertinent quality actions were done for measures and activities done by the clinician and group. In addition, validation guidance clarifications can be found within the improvement activities validation document at the *MIPS Data Validation Document* link.

Comment: A few commenters asserted that CMS should remunerate QCDRs for the associated cost of performing pre-submission audits of the 3 performance categories.

Response: We disagree that we should have to remunerate QCDRs for the cost associated with validating QCDR data prior to submission for the three performance categories, as we believe validation is a part of the duties of a QCDR.

Comment: A few commenters stated that if the proposal is finalized, it should not be finalized for the 2020 self-nomination process as it does not give QCDRs or clinicians enough time to incorporate it into their processes and workflows.

Response: We clarify that this policy will not be required by QCDRs or qualified registries for the 2020 self-nomination process. As stated in the CY 2020 PFS proposed rule (84 FR 40811), we proposed that beginning with the 2021 performance period and for future years, to require QCDRs to support three performance categories: Quality, improvement activities; and Promoting Interoperability. This policy would take effect beginning with the 2023 MIPS payment year or the 2021 performance period. Specifically, the 2021 self-nomination period which begins on July 1, 2020 and ends on September 1, 2020, which gives QCDRs sufficient time to incorporate this reporting into their workflows. As mentioned above, based on our review, a majority of QCDRs and qualified registries already support all three performance categories, and therefore, they should already have it incorporated into their processes and workflows. To clarify, this policy requires that QCDRs and qualified registries support all three performance categories, but does not require that an eligible clinician or group to report all three performance categories through a QCDR or qualified registry. We note in this final rule that the 2021 performance period corresponds to the 2023 MIPS payment years and are updating our policies to reflect this terminology for consistency.

Comment: One commenter stated that the proposals to require QCDRs and qualified registries to support the reporting of the quality, Promoting Interoperability, and improvement activities performance categories does not appropriately account for use cases in which a health IT vendor acts as both an EHR and a QCDR/qualified registry. The commenter asked CMS to exempt organizations that are EHRs that also have met the requirements to be considered a QCDRs/Qualified Registries from the requirement for QCDRs/Qualified Registries to support all three performance categories if the vendor offers the ability to support the reporting of the remaining performance categories through their EHR. The commenter further believed that a health IT vendor who supports all performance categories, regardless of whether it is accomplished via EHR or qualified registry/QCDR, will suffice in terms of supporting clinicians who participate in MIPS. One commenter expressed the belief that health IT vendors should be held to the same standards as QCDRs and qualified registries, particularly considering that EHRs contain much of the data needed to report on any of the three categories, and as such, CEHRT should be able to support and report on all three performance categories.

Response: We believe that a qualified registry or QCDR should support all three performance categories, regardless of the other types of services they may provide. Health IT vendors and other organizations who act as an EHR in addition to being a QCDR or qualified registry would not be exempt from this requirement. The intent of requiring QCDRs and qualified registries to support all three performance categories is to reduce reporting burden on behalf of the clinician who may have previously been forced to use multiple submission types to report to CMS for

purposes of MIPS. In addition, we appreciate the commenter's feedback that health IT vendors should be held to the same standards as QCDRs and qualified registries, and may consider this feedback in future rulemaking. We also believe it is important for all approved QCDRs and qualified registries to be able to submit MIPS data in all MIPS performance categories as needed by their MIPS eligible clinicians, groups, and virtual groups. Our policy goal is to reduce burden on clinicians and groups by ensuring they can use a single third party intermediary to submit all data on quality, improvement activities, and promoting interoperability. Creating an exception if multiple intermediaries are owned by the same organization would be inconsistent with this goal. For example, some organizations could require an eligible clinician or group to pay two separate fees, one to use its QCDR or qualified registry, and another to use its EHR. We would like to streamline services in order to give eligible clinicians and groups a less burdensome reporting experience. We note that we will be monitoring changes in this space.

Comment: A few commenters stated that the proposed exemption for qualified registries and QCDRs whose participants receive an exemption under the special status categories for the Promoting Interoperability performance category is unclear. Specifically, a commenter stated that CMS does not provide an indication as to the percentage of participants that would have to be exempt for the qualified registry or QCDR to not have to accept and submit Promoting Interoperability data, while another commenter sought clarity as to which specific specialties would be subject to the exemption.

Response: QCDRs and qualified registries are expected to support data submission in the MIPS performance category for Promoting Interoperability for each of its MIPS eligible clinicians, groups or virtual groups to which this performance category applies. However, a third party could be excepted from this requirement if all of the third party intermediary's MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) or (5) or § 414.1380(c)(2)(i)(C)(1)(7) or § 414.1380(c)(2)(i)(C)(*9*) (84 FR 40811). Accordingly, a third party intermediary may not be required to submit data for the Promoting Interoperability performance category if it only represents MIPS eligible clinicians, groups, and virtual groups that are eligible for reweighting under the Promoting Interoperability performance category. For example, as discussed in the CY 2019 PFS final rule (83 FR 59819 through 59820), physical therapists generally are eligible for reweighting of the Promoting Interoperability performance category to zero percent of the final score; therefore, under this exception, a QCDR or qualified registry that represents only physical therapists that reweighted the Promoting Interoperability performance category to zero percent of the final score, would not be required to support the Promoting Interoperability performance category. Similarly, a QCDR or qualified registry may not be required to support the Promoting Interoperability performance category if it supported only following clinician types: Occupational therapists; qualified speech-language pathologists; qualified audiologists; clinical psychologists; and registered dieticians or nutrition professionals, as described in § 414.1380(c)(2)(i)(A)(4). In contrast, a QCDR or qualified registry cannot be excepted from this requirement and must be able to submit data for the Promoting Interoperability performance category so long as it supports any clinician, group or virtual group that uses CEHRT and is not identified as eligible for reweighting of the Promoting Interoperability performance category. We refer readers to section III.K.3.c.(4) of this final rule for additional details on the Promoting Interoperability performance category.

After consideration of the comments, we are finalizing our proposals with technical modifications for clarity and consistency with the existing provisions of § 414.1400. Specifically, we are finalizing changes to § 414.1400(a)(2) to state that beginning with the 2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the MIPS performance categories identified in the regulation, and Health IT vendors must be able to submit data for at least one such category. We are also finalizing our proposal to amend § 414.1400(a)(2)(iii), as proposed, to state that for the Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) or (*5*) or § 414.1380(c)(2)(i)(C)(*1*) through (*7*) or § 414.1380(c)(2)(i)(C)(*9*).

(2) Approval Criteria for Third Party Intermediaries

We refer readers to § 414.1400(a)(4) and the CY 2019 PFS final rule (83 FR 59894 through 59895, 60088) for previously finalized policies related to the approval criteria for third party intermediaries.

Based on experience with third party intermediaries thus far, in the CY 2020 PFS proposed rule (84 FR 40811), we proposed to adopt two additional criteria for approval at § 414.1400(a)(4) to ensure continuity of services to MIPS eligible clinicians, groups, and virtual groups that utilize the services of third party intermediaries. Specifically, we have experienced instances where a third party intermediary withdraws mid-performance period, which impacts the clinician or group's ability to participate in the MIPS program, through no fault of their own. We proposed two changes to help prevent these disruptions (84 FR 40811 through 40812). First, we proposed at § 414.1400(a)(4) to add a new paragraph (v) to establish that a condition of approval for a third party intermediary is for the entity to agree to provide services for the entire performance period and applicable data submission period (84 FR 40812). In addition, we proposed at § 414.1400(a)(4) to add a new paragraph (vi) to establish that a condition of approval is for a third party intermediary to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate data submission mechanism or third party intermediary according to a CMS approved transition plan (84 FR 40812). We believe it is important to condition the approval of a third party intermediary on the entity agreeing to follow this process so that in the case a third-party intermediary fails to meet its obligation under the proposed § 414.1400(a)(4)(v) to provide services for the entire performance period and corresponding data submission period, the third party intermediary and the clinicians, groups, and virtual groups it serves have common expectations of the support the third party intermediary will provide to its users in connection with its withdrawal (84 FR 40812). We believe these proposed conditions of approval will help ensure that entities seeking to become approved as third party intermediaries are aware of the expectations to provide continuous service for the duration of the entire performance period and corresponding data submission period, will help reduce the extent to which the clinicians, groups, and virtual groups are inadvertently impacted by a third

party intermediary withdrawing from the program, and will help clinicians, groups, and virtual groups avoid additional reporting burden that may result from withdrawals mid-performance period (84 FR 40812). We note that we proposed, if CMS determines that a third party intermediary has ceased to meet either of these proposed criteria for approval, CMS may take remedial action or terminate the third party intermediary in accordance with § 414.1400(f) (84 FR 40812). We also refer readers to sections III.K.3.g.(3) and III.K.3.g.(4) of this final rule where we discuss these topics for QCDRs and qualified registries specifically.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to require third party intermediaries to attest that they will provide services for the entire performance period and to agree to provide a transition plan to an alternative data submission mechanism or third-party intermediary prior to discontinuing services.

Response: We thank the commenters for their support.

Comment: One commenter stated that the requirement to provide transition plans for participants in the case of service discontinuation should not be approved as it would be extremely burdensome for a third party intermediary to have to do individual transition plans given that the decision in this circumstance lies with the clinicians and their practices to make such a transition. In place of the requirement, the commenter recommended that a ''CMS-approved transition advisory plan'' be developed due to its belief that additional requirements are unnecessary, without proven benefit, and would not lead to any earlier identification of quality issues. The same commenter encouraged CMS to remain sensitive to and flexible in dealing with any extenuating circumstances outside the registry's direct control that could lead to or cause an interruption in MIPS reporting services.

Response: We thank the commenter for their suggestions. We clarify that in instances where a clinician or group is leaving a third party intermediary on its own volition, a transition plan, while encouraged, is not required from a QCDR or a qualified registry. Our proposal addresses the opposite scenario—if QCDRs and qualified registries discontinue services to their MIPS eligible clinician, group or virtual group during a performance period. We believe it is important for a third party intermediary to agree that prior to discontinuing services, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate submitter type (and as needed alternate collection type) or third party intermediary according to a CMS approved a transition plan. We have experienced scenarios where QCDRs and qualified registries have withdrawn from participation in the middle of the performance period, which causes inadvertent burden on eligible clinicians and groups who have to then scramble to find alternative methods of submitting their data to us in order to satisfy the reporting requirements for a given performance year. Eligible clinicians and groups that use qualified registries or QCDRs, utilize them as a way to mitigate reporting burden. We disagree that requiring a transition plan is unnecessary and without benefit; QCDRs and qualified registries should explain their mitigation strategy in informing their clients on alternative methods of reporting. We appreciate the commenter's recommendation that we develop a ''CMS-approved transition advisory plan'', but disagree that it is appropriate. The strategy utilized in transitioning clients off a QCDR or qualified registry's platform should be left to the QCDR or qualified registry to determine, based on their size, volume of clinicians and groups, the timing to which they will completely discontinue service as a QCDR or registry, and other factors that may be unique to a given QCDR/qualified registries specific business relationship with a clinician. We believe it is important for each transition plan to take into consideration the above mentioned factors, which is why we believe it is appropriate to provide flexibility to the third party intermediaries to craft a transition plan for our review and approval. While we understand that sometimes issues arise outside of the registry's direct control, impacting a registry's ability to provide services, we believe that a transition plan should be required regardless of the reason that the third party intermediary is discontinuing services.

After consideration of the comments, we are finalizing at § 414.1400(a)(4), as proposed, to add a new paragraph (v) to establish that a condition of approval for a third party intermediary is for the entity to agree to provide services for the entire performance period and applicable data submission period. Also, we are finalizing at § 414.1400(a)(4) to add paragraph (vi) with modification. Instead of requiring the third party intermediary to support the transition of such MIPS eligible clinician, group, or virtual group to an alternate data submission mechanism or third party intermediary, we are finalizing that the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate submitter type, or for any measures on which data has been collected, alternate collection type or third party intermediary according to a CMS approved a transition plan. This modification to the specific submission terms in this policy is to be consistent with the terminology used in §§ 414.1325 and 414.1335 (83 FR 59749 through 59754). As such, we are finalizing at § 414.1400(a)(4) to add a new paragraph (vi) to establish that a condition of approval is for the third party intermediary to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan.

Third party intermediaries are not required to support the transition of MIPS eligible clinicians, groups, or virtual groups to an alternate collection type for measures on which no data has been collected. We note that for QCDR measures, supporting the transition to an alternate collection type may not be feasible in every case. If we determine that a third party intermediary has ceased to meet either of these criteria for approval, we may take remedial action or terminate the third party intermediary in accordance with § 414.1400(f).

(3) Qualified Clinical Data Registries (QCDRs)

In the CY 2020 PFS proposed rule (84 FR 40812 through 40814), we proposed: (a) QCDR approval criteria; and (b) various policies related to QCDR measures. These proposed policies would also affect the QCDR self-nomination process.

(a) QCDR Approval Criteria

We generally refer readers to section 1848(m)(3)(E) of the Act, as added by section 601(b)(1)(B) of the American Taxpayer Relief Act of 2012, which requires the Secretary to establish requirements for an entity to be

considered a Qualified Clinical Data Registry (QCDR) and a process to determine whether or not an entity meets such requirements. We refer readers to section 1848(m)(3)(E)(i), (v) of the Act, the CY 2019 PFS final rule (83 FR 60088), and § 414.1400(a)(4) through (b) for previously finalized policies about third party intermediaries and QCDR approval criteria. In the CY 2020 PFS proposed rule (84 FR 40812 through 40814), we proposed to add to those policies to require QCDRs to: (a) Support all three performance categories where data submission is required; (b) engage in activities that will foster improvement in the quality of care; and (c) enhance performance feedback requirements.

(i) Requirement for QCDRs To Support All Three Performance Categories Where Data Submission Is Required

In the CY 2020 PFS proposed rule (84 FR 40811), we proposed to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In this section, we discuss QCDRs specifically. As previously stated in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), section 1848(q)(1)(E) of the Act encourages the use of QCDRs in carrying out MIPS. Although section 1848(q)(5)(B)(ii)(I) of the Act specifically requires the Secretary to encourage MIPS eligible clinicians to use QCDRs to report on applicable measures for the quality performance category, and section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through QCDRs, the statute does not specifically address use of QCDRs for the other MIPS performance categories (81 FR 77363). Although we previously could have limited the use of QCDRs to assessing only the quality performance category under MIPS and providing performance feedback, we believed (and still believe) it would be less burdensome for MIPS eligible clinicians if we expand QCDRs' capabilities (81 FR 77363). By allowing QCDRs to report on quality measures, improvement activities, and Promoting Interoperability measures, we alleviate the need for individual MIPS eligible clinicians and groups to use a separate mechanism to report data for these performance categories (81 FR 77363). It is important to note that QCDRs do not need to submit data for the cost performance category since these measures are administrative claims-based measures (81 FR 77363).

As noted above, based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088), the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability.

Through education and outreach, we have become aware of stakeholders' desires to have a more cohesive participation experience across all performance categories under MIPS. Specifically, we have heard of instances where clinicians would like to use their QCDR for reporting the improvement activities and promoting interoperability performance categories, but their particular QCDR does not support all categories, only quality. This results in the clinician needing to enter into a business relationship with another third party to complete their MIPS reporting or leverage a different submitter type or submission type, which can create additional burden to the clinician. We believe that requiring QCDRs to be able to support these performance categories will be a step towards addressing stakeholders concerns on having a more cohesive participation experience across all performance categories under MIPS. In addition, we believe this proposal will help to reduce the reporting burden MIPS eligible clinicians and groups face when having to utilize multiple submission mechanisms to meet the reporting requirements of the various performance categories. Furthermore, as we move to a more cohesive participation experience under the MIPS Value Pathways (MVP), as discussed in the CY 2020 PFS proposed rule (84 FR 40732 through 40745), we believe this proposal will assist clinicians in that transition. We also refer readers to section III.K.3.a. of this final rule where the MIPS MVP is discussed.

Based on our review of existing 2019 QCDRs through the 2019 QCDR Qualified Posting, approximately 92 QCDRs, or about 72 percent of the QCDRs currently participating in the program, are supporting all three performance categories. When the CY 2020 PFS proposed rule was published the 2019 QCDR Qualified Posting was available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/347/2019%20QCDR%20Qualified%20Posting_Final_v3.xlsx* (84 FR 40813). Since the publication of that proposed rule, the link has since been updated and is now available in the Quality Payment Program Resource Library at *https://qpp.cms.gov/about/resource-library* by searching for the ''2019 QCDR Qualified Posting.'' In addition, in our review of prior data through previous qualified postings for the 2017 and 2018 performance periods, we have observed that a majority of the QCDRs participating in the program supported the three performance categories that require data submission. In 2017, 73 percent (approximately 83 QCDRs) and in 2018, 73 percent (approximately 110 QCDRs) have supported all three performance categories. While we do not yet have data to share for how clinicians participated in 2019 (year 3), we do want to indicate that we have observed from 2017 (year 1) to 2018 (year 2) approximately 24 percent increasing to 36 percent of clinicians have used their QCDR/qualified registry for submitting for all 3 performance categories. We believe when this policy becomes finalized, more MIPS eligible clinicians may want to use this method as a burden reduction on data submission. Based on this data, we believe it is reasonable to want to continue to strengthen our policies at § 414.1400(a)(2) by requiring that QCDRs have the capacity to support the reporting requirements of the quality, improvement activities, and promoting interoperability performance categories.

Therefore, beginning with the 2021 performance period and for future years, we proposed to require QCDRs to support three performance categories: Quality, improvement activities, and Promoting Interoperability (84 FR 40813). We note that the 2021 performance period corresponds to the 2023 MIPS payment years and are updating our policies here in this final rule to reflect this terminology for consistency. Additionally, for reasons, as discussed above, we proposed to amend § 414.1400(a)(2) to state, beginning with the 2023 MIPS payment year (2021 performance period) and for all future years, for the following MIPS performance categories, QCDRs must be able to submit data for all categories, and Health IT vendors must be able to submit data for at least one category: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability with an exception. As discussed in the CY 2020 PFS proposed rule (84 FR 40811), we proposed that based on the amendment to § 414.1400(a)(2)(iii), for the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party

could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4), (c)(2)(i)(A)(5), (c)(2)(i)(C)(1) through (c)(2)(i)(C)(7), or (c)(2)(i)(C)(*9*) (84 FR 40813). As part of this proposal, we would require QCDRs to attest to the ability to submit data for these performance categories, as applicable, at time of self-nomination.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to require QCDRs to support the reporting of data for the quality, Promoting Interoperability, and the improvement activities performance categories, as well as the exemption for QCDRs who serve specialties that are exempt from the Promoting Interoperability performance category. Some commenters noted their QCDRs are already submitting data on all three performance categories, while other QCDRs report measures in the Quality Category and attest to improvement activities.

Response: We thank commenters for their support.

Comment: One commenter noted that the proposal should not be considered until after the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Rule (21st Century Cure Act) final rule is published and the updated standards are implemented.

Response: We understand the interest in coordinating with the updates to standards that may be included in the 21st Century Cures Act final rule, however we do not believe that the proposals under the 21st Century Cures Act will have a significant impact on the ability of QCDRs to report measures for the Promoting Interoperability category. We note this requirement was proposed with a delayed implementation, beginning with the 2023 MIPS payment year (2021 performance period), which should accommodate timing for any updates to standards. When the 21st Century Cures Act final rule is published we will determine if additional modifications are necessary and may address in future rule making.

Comment: One commenter requested CMS provide additional clarification regarding the number of measures from each performance category that will be required for approval.

Response: As described in the CY 2017 Quality Payment Program final rule (81 FR 77368), QCDRs and qualified registries are required to support the minimum number of measures to meet the reporting requirements of the Quality performance category. Through the finalization of the policy to require QCDRs and qualified registries to support all three performance categories in this final rule, we encourage third parties to support the minimum number of measures and activities to support the Promoting Interoperability performance category as discussed in § 414.1375 (83 FR 59798 through 59817) and Improvement Activities performance category as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77185, in order to offer a complete reporting experience to eligible clinicians and groups.

Comment: One commenter questioned whether the QCDR will be required to audit data submitted for all performance categories. One commenter stated their belief that if the proposal is finalized, CMS should define more clearly how improvement activities should be documented to help standardize auditing by third party intermediaries and alleviate any additional burden associated with the requirement.

Response: Under our current data validation processes, as described in the CY 2017 Quality Payment Program final rule (81 FR 77368 through 77369) and (81 FR 77384 through 77385), QCDRs and qualified registries are required to provide information on their sampling methodology. For example, it is encouraged that 3 percent of TIN/NPIs submitted be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of 5 patients (with a maximum sample of 50 patients). We would expect that this review of patient medical records would be done to validate that the pertinent quality actions were done for measures and activities done by the clinician and group. In addition, validation guidance clarifications can be found within the improvement activities validation document at the MIPS Data Validation Document link. With regards to auditing whether improvement activities have been completed by a clinician or group, it is important for a third party intermediary to validate that an action has been done through review of medical records or other forms of documentation that will indicate that the quality action and/or improvement activity has been completed.

After consideration of the comments, we are finalizing our proposals with technical modifications for clarity and consistency with the existing provisions of § 414.1400. As discussed in section III.K.3.g.(1) of this final rule, we are amending § 414.1400(a)(2) to state that beginning with the 2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the MIPS performance categories identified in the regulation, and Health IT vendors must be able to submit data for at least one such category. We are also finalizing our proposal to amend § 414.1400(a)(2)(iii), as proposed, to state that for the Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) or (*5*) or § 414.1380(c)(2)(i)(C)(*1*) through (*7*) or § 414.1380(c)(2)(i)(C)(*9*). We refer readers to section III.I.3.d.(2) of this final rule where reweighting policies are discussed. We are also finalizing that QCDRs are required to attest to the ability to submit data for these performance categories, as applicable, at time of self-nomination.

(ii) Requirement for QCDRs To Engage in Activities That Will Foster Improvement in the Quality of Care

We generally refer readers to section 1848(m)(3)(E)(i) and (v) of the Act, which requires the Secretary to establish requirements for an entity to be considered a qualified clinical data registry and a process to determine whether or not an entity meets such requirements. Section 1848(m)(3)(E)(ii)(IV) of the Act provides that in establishing such requirements, the Secretary must consider whether an entity, among other things, supports quality improvement initiatives for participants.

As detailed at § 414.1305(1) a QCDR means: For the 2019, 2020 and 2021 MIPS payment year, a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

Although ''improvement in the quality of care'' is broadly included under paragraph (2) of the definition of a QCDR at § 414.1305 in the 2019 PFS final rule (83 FR 59897), we want to further clarify how a QCDR can be successful in fostering improvement in the quality of care provided to patients by clinicians and groups. We understand putting parameters around exactly what improvement in the quality of care may be can be difficult due to the varying nature of QCDRs

organizational structures. For example, we have QCDRs that are founded by both large and small specialty societies, and healthcare systems where the volumes of services, available resources, and volume of members may vary. However, we believe QCDRs should enhance education and outreach to clinicians and groups to improve patient care.

The definition of qualified clinical data registry (QCDR) at § 414.1305(2) currently states that beginning with the 2022 MIPS payment year, an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. In the CY 2020 PFS proposed rule (84 FR 40813), we proposed policies with regards to ''foster improvement in the quality of care''.

Therefore, we proposed to add § 414.1400(b)(2)(iii) that beginning with the 2023 MIPS payment year, the QCDRs must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement and leading quality improvement initiatives (84 FR 40813). Quality improvement services may be broad, and do not necessarily have to be specific towards an individual clinical process. An example of a broad quality improvement service would be for the QCDR to provide reports and educating clinicians on areas of improvement for patient populations by clinical condition for specific clinical care criteria. Furthermore, an example of an individual clinical process specific quality improvement service would be if the QCDR supports a metric that measures blood pressure management, the QCDR could use that data to identify best practices used by high performers and broadly educate other clinicians and groups on how they can improve the quality of care they provide. We believe educational services in quality improvement for eligible clinicians and groups would encourage meaningful and actionable feedback for clinicians to make improvements in patient care. To be clear, these QCDR quality improvement services would be separate and apart from any activities that are reported on under the improvement activities performance category. We believe improvement activities can be distinguished from quality improvement services, because they are actions taken by MIPS eligible clinicians under the improvement activities performance category. Improvement activities means an activity that relevant MIPS eligible clinician, organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes (§ 414.1305). Quality improvement services, on the other hand, would be actions taken by the QCDR. While these QCDR quality improvement services could potentially overlap with an improvement activity, requirements for the improvement activities performance category would still apply to MIPS eligible clinicians and groups.

We proposed to require QCDRs to describe the quality improvement services they intend to support in their self-nomination for CMS review and approval. We intend on including the QCDR's approved quality improvement services in the qualified posting for each approved QCDR (84 FR 40813).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to require QCDRs to engage in activities that improve quality of care and further cited their appreciation for the flexibility provided by CMS to meet the requirement. A few commenters suggested that CMS should provide a minimum threshold such as sharing links to the quality improvement education website or a QCDR platform with trending performance graphs. One commenter expressed its concern the terminology being used due to its opinion that improvement activities conducted by the MIPS eligible clinician and improvement services provided by the QCDR can be confusing.

Response: We thank commenters for their support, and while we agree this proposal is important to engage QCDRs in activities that will foster improvement in the quality of care; after reviewing public comments received, we are not finalizing this proposal. However, since this policy is important to the quality of care, as well as, CMS, we want to prepare QCDRs for this policy to be considered for future rulemaking and would encourage QCDRs to start planning for this possibility. While we did not state a minimum threshold of the type of service that needs to be provided as part of our proposal, as described in the CY 2020 PFS proposed rule (84 FR 40813), we provided examples of services, such as enhanced education and outreach, or providing reports and educating clinicians on areas of improvement for patient populations by clinical condition for specific clinical care criteria. We appreciate the commenters' suggestions for providing a minimum threshold, and may consider this feedback for future rulemaking. As part of future rulemaking we may also consider requirements that would require that the QCDRs describe the activities they are proposing to support as a part of their self-nomination application, as well as the ability of the QCDR to provide this service to all the clinicians and groups it supports for a given performance period. We appreciate the concern with potential confusion between quality improvement services and improvement activities, in any future rulemaking we would be sure to clearly communicate that they are different as a part of our subregulatory guidance to educate stakeholders.

Comment: Several commenters disagreed with the proposal to require QCDRs to engage in activities that improve quality of care citing concerns that the policy is vague, unclear, and could be used in an arbitrary fashion to possibly compare or rank QCDRs. A few commenters stated that additional details are necessary regarding what activities would meet this requirement, with a few commenters expressing that in place of finalizing this proposal, CMS should search for additional alternatives or publish a separate request for information followed by rulemaking that describes this proposal in more detail so that the public can provide a more thoughtful response.

Response: We thank the commenters' for their suggestions and agree that clarity is an important part of rulemaking. We agree with commenters that there needs to be more specificity in this proposal, and therefore, are not finalizing this requirement for this rule. Additionally, even though we are not finalizing this proposal, we continue to believe this policy is important, especially in the regard that QCDR applicants can innovate ideas for quality improvement services as they self-nominate, based on their capabilities and the needs of their clinicians and groups.

We did not intend on the policy to be vague, unclear, or arbitrary but intended to provide flexibility to the QCDR as to the type of improvement service they may offer; the services offered would not be used to rank the QCDRs in any way but to serve as a helpful resource for clinicians and groups. To that end, we did not want to standardize the type of quality improvement services a QCDR should offer, and so we intentionally crafted a policy that was not overly

specific. With the understanding that QCDRs differ in size, we wanted to leave the type of service available up to the QCDR to determine what is feasible and appropriate for the clinicians and groups they support. An example of a broad quality improvement service would be for the QCDR to provide reports and educating clinicians on areas of improvement for patient populations by clinical condition for specific clinical care criteria. Furthermore, an example of an individual clinical process specific quality improvement service would be if the QCDR supports a metric that measures blood pressure management, the QCDR could use that data to identify best practices used by high performers and broadly educate other clinicians and groups on how they can improve the quality of care they provide. Our intention was not to compare QCDRs to one another, but to expand the quality improvement initiatives a QCDR could support and offer. This policy was meant to require QCDRs to describe the activities they would plan to support as a part of their self-nomination application. We will take these comments into consideration for future rulemaking.

Comment: One commenter stated their belief that if this proposal is finalized, implementation should be delayed to give QCDRs the time to develop the necessary processes and identify the resources required to develop these types of services. Several commenters stated that this would require budgeting, planning and coordinating across staff or departmental areas that may not already be in place. Others stated that it would be too difficult or infeasible for QCDRs to change their business models to adopt.

Response: As discussed in the CY 2020 PFS proposed rule (84 FR 40813), this policy was proposed with a delayed implementation beginning with the 2023 MIPS payment year (for the 2021 performance period). We understand that there may be time needed to prepare for this requirement, including time to budget, plan, coordinate from a staffing perspective, and possibly prepare for from a business perspective. Taking these public comments into account we are not finalizing this proposal in this rule. We will take these comments into consideration for future rulemaking.

Comment: Several commenters stated this policy may be unnecessary considering the reports and activities QCDRs already conduct aimed at improving quality.

Response: As stated above, we are not finalizing this policy at this time. However, we do want to clarify that while some of the activities currently being done by QCDRs could fulfill the proposal for fostering quality improvement, not all QCDRs are consistently providing these reports to their participating clinicians. We intended to provide flexibility to the QCDR as to the type of improvement service they may offer. We will consider this feedback as we develop a potential proposal for future rulemaking.

Comment: Several commenters stated that this policy would expand responsibilities of QCDRs beyond their initially intended functions. Other commenters stated that this would create undue burden especially for small QCDRs.

Response: As stated above, we are not finalizing this policy at this time. However, we believe that there are many existing QCDRs that already provide quality improvement services, even outside of the Quality Payment Program. Our vision for QCDRs requires the need for evolvement by the QCDRs to potentially providing additional services that what was initially required under the legacy PQRS program or under the first few years of MIPS. We do not believe that such a policy would create undue burden on smaller QCDRs. We will take this feedback into consideration when developing a potential proposal for future rulemaking.

After consideration of the comments, we are not finalizing our proposals. Specifically, we are not finalizing at § 414.1400(b)(2)(iii) that beginning with the 2023 MIPS payment year, the QCDRs must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement and leading quality improvement initiatives. We are also not finalizing the proposed requirement that QCDRs describe the quality improvement services they intend to support in their self-nomination for CMS review and approval. While we are not including the QCDR's approved quality improvement services in the qualified posting for each approved QCDR, we will consider proposing this requirement in subsequent future rulemaking, and would encourage QCDRs to prepare as such.

(iii) Enhanced Performance Feedback Requirement

Section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through QCDRs. In addition, in establishing the requirements, the Secretary must consider, among other things, whether an entity provides timely performance reports to participants at the individual participant level (section 1848(m)(3)(E)(ii)(III) of the Act). Currently, CMS requires QCDRs to provide timely performance feedback at least 4 times a year on all of the MIPS performance categories that the QCDR reports to CMS (82 FR 53812). Based on our experiences thus far under the Quality Payment Program, we agree that providing feedback at least 4 times a year is appropriate. However, in the future CMS would like to see, and therefore, encourages QCDRs, to provide timely feedback on a more frequent basis more than 4 times a year. Receipt of more frequent feedback will help clinicians and groups make more timely changes to their practice to ensure the highest quality of care is being provided to patients. We see value in providing more timely feedback to meet the objectives [117] of the Quality Payment Program in improving the care received by Medicare beneficiaries, lowering the costs to the Medicare program through improvement of care and health, and advance the use of healthcare information between allied providers and patients. We also believe there is value in this performance feedback, and therefore, encourage QCDRs to work with their clinicians to get the data in earlier in the reporting period so the QCDR can give meaningful, timely feedback.

In the QCDR performance feedback currently being provided to clinicians and groups, we have heard from stakeholders that that not all QCDRs provide feedback the same way. We have heard through stakeholder comments that some QCDR feedback contains information needed to improve quality, whereas other QCDR feedback does not supply such information due to the data collection timeline. Additionally, we believe that clinicians would benefit from feedback on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure or QCDR measure) within the QCDR they are reporting through, so they can identify areas of measurement in which improvement is needed, and furthermore, they can see how they compare to their peers based within a QCDR, since the feedback provided by the QCDR would be limited to those who reported on a given measure using that specific QCDR.

[117] Quality Payment Program Overview. *https://qpp.cms.gov/about/qpp-overview.*

Therefore, we proposed a change so that QCDRs structure feedback in a similar manner (84 FR 40814). We proposed a new paragraph at § 414.1400(b)(2)(iv), beginning with the 2023 MIPS payment year, to require that QCDRs provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR (84 FR 40814). (*Note:* Since we are not finalizing § 414.1400(b)(2)(iii) (see section III.K.3.g.(3)(a)(ii) of this final rule), the previously proposed § 414.1400(b)(2)(iv) will now become § 414.1400(b)(2)(iii).) Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period. We also solicited comment on other exceptions that may be necessary under this requirement.

We also understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. We believe QCDR internal comparisons can still help MIPS eligible clinicians identify areas where further improvement is needed. The ability for MIPS eligible clinicians to be able to know in real time how they are performing against their peers, within a QCDR, provides immediate actionable feedback. We believe this provides value gained for clinicians as the majority of QCDRs are specialty specific or regional based, therefore the clinician can gain peer comparisons that are specific to their peer cohort, which can be specialty specific or locality based. Furthermore, we also proposed to strengthen the QCDR self-nomination process at § 414.1400(b)(1) to add that beginning with the 2023 MIPS payment year, QCDRs are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(b)(2)(iii)) (84 FR 40814). We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal for QCDRs to provide enhanced performance feedback at least 4 times a year including comparisons to other clinicians who reported the same measure, at minimum. Commenters expressed their belief that the feedback and comparison is very beneficial to their participants and helps them identify potential areas for performance improvement as compared to their peers.

Response: We thank commenters for their support.

Comment: A few of the commenters stated their opinion that CMS should finalize exceptions for occasions when the QCDR does not receive data from the clinician until the end of the performance period.

Response: As proposed in the CY 2020 PFS proposed rule (84 FR 40814), we also stated that exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period. We would depend on the QCDRs to let us know as soon as possible when there are issues that arise that would cause a delay in providing performance feedback.

Comment: Another commenter stated its opinion that while it agrees with the intent of providing enhanced feedback at least 4 times per year, without requiring data be submitted regularly and consistently across all collection types, improvement in individual patient and population health outcomes may not be experienced as originally intended in the MACRA legislation.

Response: We appreciate the feedback on requiring data to be submitted regularly and consistently across all collection types, but believe that improvements in individual patients and population health outcomes can still be experienced in smaller cohorts on a QCDR by QCDR basis.

After consideration of the comments, we are finalizing our proposal with technical modifications to update the numbering, § 414.1400(b)(2)(iv) will now become § 414.1400(b)(2)(iii) because we did not finalize the requirement for QCDRs to engage in activities that would foster improvement in the quality of care proposal at § 414.1400(b)(2)(iii) per section III.K.3.g.(3)(a)(ii) of this final rule. Specifically, we are finalizing at § 414.1400(b)(2)(iii), beginning with the 2023 MIPS payment year, to require that QCDRs provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR. Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period. In addition, we are also finalizing our proposal as proposed, to strengthen the QCDR self-nomination process at § 414.1400(b)(1) to add that beginning with the 2023 MIPS payment year, QCDRs are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(b)(2)(iii)) (84 FR 40814).

In addition, the current performance period begins January 1 and ends on December 31st, and the corresponding data submission deadline is typically March 31st as described at § 414.1325(e)(1). As discussed above, we have heard from QCDR stakeholders that in some instances clinicians wait until the end of the performance period to submit data to the third party intermediary, who are then unable to provide meaningful feedback to their clinicians 4 times a year. Therefore, in the CY 2020 PFS proposed rule (84 FR 40814), we sought comment for future notice-and-comment rulemaking on whether we should require MIPS eligible clinicians, groups, and virtual groups who utilize a QCDR to submit data throughout the performance period, and prior to the close of the performance period (that is, December 31st). We also sought comment for future notice-and-comment rulemaking, on whether clinicians and groups can start submitting their data starting April 1 to ensure that the QCDR is providing feedback and the clinician or group during the performance period (84 FR 40814). This would allow QCDRs some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.

While we are not summarizing and responding to these comments we received in this final rule, we thank the commenters for their responses and will take them into consideration as we develop future policies for QCDRs.

(b) QCDR Measures

We refer readers to § 414.1400(b)(1), the CY 2018 Quality Payment Program final rule (82 FR 53814) and the CY 2019 PFS final rule (83 FR 59898 through 59900) for our previously established policies for the QCDR measure self-nomination process. In the CY 2020 PFS proposed rule (84 FR 40814 through 40819), we proposed policies related to: (a) Considerations for QCDR measure approval; (b) requirements for QCDR measure approval; (c) considerations for QCDR measure rejections; (d) the approval process; and (e) QCDR measures that have failed to reach benchmarking thresholds. These are discussed in detail below.

(c) QCDR Measure Requirements

In this final rule, we are clarifying that the newly finalized QCDR measure considerations and requirements for approval apply to all QCDR measures, regardless of whether they have been approved for previous performance periods or are new QCDR measures for the 2021 performance period and future years. We will not be grandfathering in previously approved QCDR measures.

(i) QCDR Measure Considerations and Requirements for Approval or Rejection

Through education and outreach, we have heard stakeholders' concerns about the complexity of reporting when there is a large inventory of QCDR measures to choose from, and believe our proposals will help to ensure that the measures made available in MIPS are meaningful to a clinician's scope of practice. In the CY 2020 PFS proposed rule (84 FR 40814), we proposed to codify established QCDR measure considerations and proposed, beginning with the CY 2021 performance period, a number of QCDR measure specific requirements, that would generally align with MIPS measure policies, which can be found in the CY 2018 Quality Payment Program final rule (82 FR 53636), and as described in the CY 2020 PFS proposed rule (84 FR 40745 through 40752), as well as section III.K.3.c.(1) of this final rule.

(A) QCDR Measure Considerations

(aa) Previously Finalized QCDR Measure Considerations

We generally refer readers to the § 414.1400(b)(3), CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375) and the CY 2019 PFS final rule (83 FR 59900 through 59902) for previously finalized standards and criteria used for selecting and approving QCDR measures. QCDR measures are reviewed for inclusion on an annual basis during the QCDR measure review process that occurs once the self-nomination period closes (82 FR 53810). All previously approved QCDR measures and new QCDR measures are currently reviewed on an annual basis to determine whether they are appropriate for the program (82 FR 53811). The QCDR measure review process occurs after the self-nomination period closes on September 1st. QCDR measures are not finalized or removed through notice and comment rulemaking; instead, they are currently approved or not approved through a subregulatory processes (82 FR 53639).

In the CY 2019 PFS final rule (83 FR 59902), we finalized our proposal to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.

In the CY 2020 PFS proposed rule (84 FR 40815), we proposed to codify a number of those previously finalized QCDR measure considerations that we had finalized in the CY 2019 PFS final rule (83 FR 59902). We also proposed to amend § 414.1400 by adding § 414.1400(b)(3)(iv) to include the following previously finalized QCDR measure considerations for approval (84 FR 40815):

- Preference for measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain of care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.

More information on QCDR measure approval criteria can be found in the QCDR/qualified registry Self-Nomination Tool-Kit in the Quality Payment Program Resource Library.

We refer readers to the CY 2020 PFS proposed rule (84 FR 40815) and section III.K.3.g.(3)(c)(i)(B) of this final rule where we discuss changes to the following previously finalized considerations into requirements:

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

We did not receive public comments on this proposal.

Therefore, we are finalizing our proposal as proposed by adding § 414.1400(b)(3)(iv) to include the following QCDR measure considerations for approval:

- Preference for measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain of care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.

We refer readers to section III.K.3.g.(3)(c)(i)(B)(aa) of this final rule, for a discussion regarding the following previously finalized considerations into requirements (84 FR 40815):

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

(bb) New QCDR Measure Considerations for Approval

(AA) QCDR Measure Availability

In the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), we finalized a policy beginning with the 2018 performance period, that allowed QCDRs to seek permission from another QCDR to use an existing and approved QCDR measure. If a QCDR would like to report on an existing QCDR measure that is owned by another QCDR, they must have permission from the QCDR that owns the measure that they can use the measure for the performance period. Permission must be granted at the time of self-nomination, so that the QCDR that is using the QCDR measure can include written proof of permission for CMS review and approval. We also finalized in the CY 2018 Quality Payment Program final rule (82 FR 53814) that once QCDR measures are approved, we will assign QCDR measure IDs, and the same measure IDs must be used by the other QCDRs that have permission to also report on the measure.

We generally encourage QCDR measure owners to permit other QCDRs to report their measures on behalf of MIPS eligible clinicians for purposes of MIPS. To the extent that QCDR measure owners limit the availability of their measures, such limitations may adversely affect a QCDR's ability to benchmark the measure, the robustness of the benchmark, or the comparability of MIPS eligible clinicians' performance results on the measure. For these reasons, we proposed to amend § 414.1400 to add paragraph (b)(3)(iv)(H) to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS (84 FR 40815). If CMS determines

that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also acknowledge that we received several comments that were out of scope for this final rule, and therefore, are not addressing in this rule, but thank commenters for this feedback.

Comment: A few commenters supported the proposal to consider QCDR measure availability as part of the QCDR measure approval process due to their beliefs that it would encourage harmonization and collaboration among QCDRs while reducing duplication resulting from the unwillingness of some QCDRs to share measures.

Response: We thank commenters for their support.

Comment: Several commenters stated that CMS should provide an opportunity for QCDR measure owners to respond to allegations of unavailability before this is allowed to be a consideration in the measure approval process.

Response: We agree that QCDR measure owners should be given a chance to respond to instances where there is alleged blocking of the use of a QCDR measure. Therefore, we request that QCDRs keep documentation as to why a QCDR measure licensing agreement could not be reached, and on a case by case basis we will review the information on why the QCDR measure was not made available to another QCDR. We would expect that QCDR measure owners would be able to provide evidence to support their claim, should it be requested, as to why a given QCDR should not be allowed to use their QCDR measure.

Comment: Many commenters disagreed with the proposal to consider the extent to which a QCDR measure is available to other QCDRs as part of the measure approval process citing concerns regarding inappropriate or inconsistent implementation, incorrect understanding of measure specifications, and lack of standardized data methods resulting in inaccurate benchmarking by the borrowing QCDR. Another commenter stated they would consider the sharing of measures if the other QCDR adhered to certain standards and terms set out by the QCDR measure owner.

Response: We thank the commenters for raising these concerns. To respond, we first clarify that the intent of this proposal was to ensure that all QCDR measures that are considered for a given performance period, are readily available for other QCDRs to license. In practice, this would mean that should the borrowing QCDR meet the terms of a QCDR measure owner's license agreement, the borrowing QCDR should be able to report on the measure. We do not dictate what is to be included in a QCDR measure licensing agreement, or if fees and to what amount are tied to QCDR measure licensure, and ultimately defer to the QCDR measure owner, borrower, and their respective legal teams to come to an agreement. We would expect that if QCDRs decide to require a QCDR measure licensure agreement for its QCDR measures, it would include the QCDR measure owner's terms of use. The terms may include implementation criteria to ensure that the measure is programmed and collected in a way that is consistent with what the QCDR measure owner intends, thereby avoiding concerns with inappropriate or inconsistent implementation. In the CY 2019 PFS final rule (83 FR 59895 through 59897), we finalized changes to the definition of a QCDR at § 414.1305 that beginning with the 2022 MIPS payment year, that a QCDR is an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. We believe that QCDRs that are approved based on the revised QCDR definition for the 2022 MIPS payment year and future years, will be able to understand measure specifications since they are required to have measure development expertise and thereby understand measure specifications in order to be approved as a QCDR. Furthermore, as a part of the QCDR measure license user agreement, QCDR measure owners could include the data standardization methods they wish to be used to ensure consistent data collection, to ensure that borrowing QCDRs are utilizing the same standards consistently. We believe approved QCDRs should be able to comprehend and adhere to a preferred standardized data methodology, should the QCDR measure owner have one. In addition, QCDRs that are approved for the 2020 performance period and future years, should be able to utilize standardized data methodologies based on their measure experience. For QCDR measure owners that implement QCDR measure licensing agreements which include terms of use, they may come to find instances where a borrowing QCDR does not meet their terms prior to granting permission to borrowing the measure. We would expect QCDR measure owners to be able to provide evidence to justify instances where their measure was made available but ultimately could not be borrowed by another QCDR, for CMS' consideration on a case-by-case basis. Our intention with this policy is to move away from having duplicative measures in the program, simply because QCDRs are unwilling to license their QCDR measures to one another. Continuously retaining duplicative QCDR measures in the program because QCDRs are unwilling to license measures to one another is counterintuitive to the Meaningful Measure Initiative, and leads to measure bloat. In instances where CMS finds that QCDRs are blocking the use of their QCDR measure from other QCDRs without any evidence that proves the borrowing QCDR is unable to meet the QCDR measure owner's terms, we will likely approve another similar QCDR measure over this one. All factors will be considered prior to CMS determining which QCDR measure will continue on in the program.

Comment: Some commenters were concerned with the dilution of important feedback that is needed to drive key improvements in care.

Response: We disagree that allowing other QCDRs to borrow a QCDR's measure will lead to the dilution of important feedback that is needed to drive key improvements in care. Having a larger cohort of MIPS eligible clinicians reporting on a given QCDR measure will provide for more meaningful data that will give MIPS eligible clinicians and groups a better idea of how they compare to their peers. Therefore, the data will provide a more accurate picture of where there are areas of improvement in order to drive quality in the care provided.

Comment: Several commenters expressed other concerns with the proposal including their beliefs that: The term ''available'' is not well defined and that CMS should elaborate on what criteria it would use to determine whether a measure is truly unavailable for reporting through other QCDRs. One commenter requested that CMS provide scenarios of what the proposal was trying to address.

Response: We thank the commenters for raising these concerns. To clarify, a QCDR measure is available when the QCDR measure owner is willing to allow other QCDRs to borrow their QCDR measure with the appropriate permissions and/or licensing. We leave measure license user agreements, expectations, and terms between the measure owner and borrower. We are

trying to address scenarios in which a QCDR measure is approved, but the QCDR measure owner does not allow any outside QCDRs to use their QCDR measure. We wish to place higher priority on measures that can be used by all clinicians participating in the program.

Comment: Some commenters stated that withholding measure approval based on lack of availability would potentially deprive clinicians of an otherwise valid and useful measure to report on.

Response: We understand the commenters concern, but want to ensure that duplicative measures are not approved because QCDRs are unwilling to license QCDR measures to one another. If a QCDR measure is not approved, it does not mean it cannot be collected on by the QCDR for purposes of quality improvement, rather the measure would not be available for MIPS eligible clinicians to use for participating under MIPS and any data collected on that measure would not be applicable for MIPS.

After consideration of the comments, we are finalizing our proposal as proposed to amend § 414.1400 to add paragraph (b)(3)(iv)(H) to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, we may not approve the measure.

(BB) QCDR Measure Addresses a Measurement Gap

As a part of the QCDR measure development process, QCDRs should conduct an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy program, PQRS; and review the most recent CMS Quality Measure Development Plan Annual Report, which is currently available for 2019 at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/2019-Quality-MDP-Annual-Report-and-Appendices.zip* and the Blueprint for the CMS Measures Management System: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf* for guidance in areas where CMS has identified gaps in quality measurement to reduce the possibility of duplicative measure development. In the CY 2020 PFS proposed rule (84 FR 40815), we proposed to amend § 414.1400 to add § 414.1400(b)(3)(iv)(I) to state that we would give greater consideration to measures for which QCDRs: (a) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and (b) utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development (84 FR 40815).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter requested clarification on whether a performance gap needs to be demonstrated by data collection via a registry over a specified period of time (for example, 2 years), or if a health care survey would sufficiently demonstrate evidence of a performance gap. The commenter also questioned what constitutes ''significant variation'' to ensure proposed measures meet CMS' expectations.

Response: In the proposed rule, we proposed that we would give greater consideration to measures for which QCDRs: (a) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and (b) utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development (84 FR 40815). The Blueprint for the CMS Measures Management System *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf* defines a performance gap as when there is known variation in performance. A measure that is considered to have a performance gap would not be considered topped out, as described in the CY 2017 Quality Payment Program final rule (81 FR 77282 through 77283). The performance gap may be identified by data submitted to the registry on the given measure, or through current clinical study citations (within the past 5 years), a health care survey would not provide sufficient evidence of a performance gap.

After consideration of the comments, we are finalizing our proposal as proposed, to amend § 414.1400 to add § 414.1400(b)(3)(iv)(I) to state that we would give greater consideration to measures for which QCDRs: (a) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and (b) utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development.

(CC) QCDRs Measures Meeting Benchmarking Thresholds

Over the first 2 years of MIPS, we have observed instances where QCDR measures have been approved for continued use in the program, but have had low reporting volumes, below the case minimum and reporting volume thresholds required for a measure to be benchmarked within the program. As described in the CY 2017 Quality Payment Program final rule (81 FR 77277 through 77282), for benchmarks to be developed, a measure must have a minimum of 20 individual clinicians or groups who reported the measure to meet the data completeness requirement and the minimum case size criteria. QCDRs should be aware of which measures are considered low-reported, since measures that do not meet benchmarking thresholds result in a 3-point floor, as described in the CY 2017 Quality Payment Program final rule (81 FR 77282). QCDR measures are reviewed and approved on an annual basis, and as a part of the review process, we review: The benchmarking file from the previous year (for example, the 2019 Quality Benchmark file, found on the Quality Payment Program Resource Library, which is available at *https://qpp.cms.gov/about/resource-library*); production submission data submitted from the previous year's data submission period; and data provided to us by the QCDRs themselves. Note to readers when the CY 2020 PFS proposed rule was published the 2019 Quality Benchmark file could be found at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip* however after publishing that rule, the link has since been updated and can now be found at the link above (*https://qpp.cms.gov/about/resource-library*) by searching for ''2019 Quality Benchmark file.''

In the CY 2020 PFS proposed rule (84 FR 40816), as discussed in our QCDR measure rejection considerations, we proposed that a QCDR measure that does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance may not continue to be

approved in the future if our proposal is finalized as proposed. We noted that this factor is parallel to what was proposed for MIPS quality measures in section III.K.3.c.(1) of the proposed rule (84 FR 40816), which is being finalized in section III.K.3.c.(1) of this final rule, and is important when considering the volume of QCDR measures that are currently in the program that have had low reporting rates year-over-year. We proposed to amend § 414.1400 to add paragraph (b)(3)(iv)(J) to state that, beginning with the 2020 performance period, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods (84 FR 40816). Those that do not, may not continue to be approved. We refer readers to section III.K.3.g.(3)(c)(ii) in the proposed rule (84 FR 40816) and section III.K.3.g.(3)(c)(ii) of this final rule, for a discussion on how QCDRs may create participation plans for existing approved QCDR measures that have failed to reach benchmarking thresholds, in order to be reconsidered for future use. We also refer readers to § 414.1330 for additional information.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters disagreed with the proposal to potentially reject QCDR measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods due to their beliefs that the policy of awarding fewer points for reporting non-benchmarked measures is enough to discourage use of these measures without further negatively impacting clinicians who have few other measures to report.

Response: While the quality scoring policy referenced by the commenters that provides a 3-point floor for measures that are submitted, but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement could have an impact on reduced reporting volumes, we believe this 2-year lifecycle and participation plan will more directly address the issue of low reported measures. We refer readers to section III.K.3.d.(1) and § 414.1380(b)(1)(i)(A) and (B) which provides details on the MIPS performance category scores.

Comment: A few commenters disagreed with the proposal due to their beliefs that it would reduce the number of available measures to a point that it would be a hardship for certain specialties to participate in MIPS; and eliminating a measure after 2 years in the program would deter QCDRs from investing in and developing new measures, maintaining existing measures, and putting forward MVP proposals. A few commenters expressed their opinion that prior to rejecting a QCDR measure that is not meeting thresholds, CMS should work with QCDR measure stewards to understand why a measure is not meeting thresholds and the importance of these measures to clinicians in specialized fields or clinicians treating less common diseases or conditions.

Response: While we appreciate the commenters concerns, we believe that maintaining low-reported measures in the program over multiple years, is counterintuitive to the Meaningful Measurement Initiative and indicative of metrics that are not of interest to the majority of clinicians within a given specialty. We believe that removing low-reported measures should not deter QCDRs in investing and developing new measures, maintaining existing measures, or putting forward MVP proposals. We believe that tracking measure reporting volumes over the years will allow QCDRs to determine whether the metric is meaningful to their eligible clinicians and group and allow for them to make revisions to existing measures or develop new measures accordingly. In addition, we are aware of instances in which measures may be low-reported due to being highly sub-specialized. Because of that, we proposed a potential mitigation strategy for QCDR measures with low-reporting volumes that do not meet benchmarking thresholds. As described in the CY 2020 PFS proposed rule (84 FR 40819), in instances where a QCDR believes a low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, the QCDR may develop and submit a QCDR measure participation plan for our consideration. The QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program. As examples, a QCDR measure participation plan could include one or more of the following: Development of an education and communication plan; update the QCDR measure's specification with changes to encourage broader participation, which would require review and approval by us; or require reporting on the QCDR measure as a condition of reporting through the QCDR. Prior to measures being eliminated from the program for a given specialty, we do conduct a review of remaining MIPS quality measures and QCDR measures to determine if there is a sufficient number of measures left. Once a participation plan is implemented, we plan to monitor the QCDR measure to determine if there is an increase in reporting volumes. We understand that the measure development process is time-consuming and costly, however. If a QCDR measure is removed because of low-reporting volumes, but a QCDR continues to collect data on the measure outside of the MIPS program, the measure could be reconsidered for the program in the future. As we develop MVPs, we will consider how each policy interacts and make any appropriate adjustments in future rulemaking.

Comment: A few commenters opposed the proposal due to their beliefs that: The 2-year period is not long enough for some measures to achieve acceptable numbers of adoption or for EHR vendors to complete data integration to support QCDR measures and that failure to achieve benchmark status does not necessarily indicate that a measure is not meaningful. In regards to the time necessary for EHR vendors to support QCDR measures, one commenter noted this process can take up to 18 months from the time a vendor learns of a new or revised set of QCDR measures until the development life cycle is complete.

Response: The 2-year timeframe was decided upon after review and consideration of benchmarking trends as indicated in the quality measure benchmark files, for the appropriate amount of time a measure typically needs to reach benchmarking thresholds. While we appreciate the commenters concerns, to clarify, EHR vendors would only be able to report on QCDR measures if they self-nominate to be a QCDR, and meet the QCDR definition, as described at § 414.1400(b)(2)(ii) in the CY 2019 PFS final rule (83 FR 59895 through 59896). Since QCDRs will be required to test their measures prior to self-nominating them, as reflected at § 414.1400(b)(3)(v)(C), it is assumed that the QCDR would have considered the time it takes for data integration from an EHR prior to testing the measure to ensure that measure is feasible. If a QCDR cannot timely complete the data integration process for a QCDR measure, it should delay self-nominating that QCDR measure until it is

implementable. We note that QCDR measures should not be submitted for consideration until they are fully developed and tested, including the ability to be supported by EHR vendors. In addition, we believe this issue is mitigated, as described in the CY 2020 PFS proposed rule (84 FR 40817) and in this final rule, by our requirement to add paragraph (b)(3)(v)(D) that QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. The data collected must demonstrate whether the QCDR measure is valid and reflects an important clinical concept(s) that clinicians wish to be measured on. By collecting data on the QCDR measure prior to self-nomination, QCDRs would be able to demonstrate whether the measure is implementable and data collection on the metric is possible.

As described in the CY 2020 PFS proposed rule (84 FR 40819), in instances where a QCDR believes a low-reported QCDR measure, that did not meet benchmarking thresholds within the 2-year timeframe, is still important and relevant to a specialist's practice, the QCDR may develop and submit a QCDR measure participation plan for our consideration. As discussed in section III.K.3.g.(3)(c)(iii) of this final rule, the QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.

Comment: A few commenters stated their opinion that CMS should delay implementation of the proposal due to their belief that it would be inappropriate to finalize a requirement after the deadline for 2020 QCDR self-nominations has passed, as well as not allowing QCDRs enough time to reevaluate their measure submission strategies.

Response: We disagree with the commenters suggestion that we delay this policy based on the passed deadline for 2020 QCDR self-nominations. We believe that enacting this policy for the 2020 performance period allows us to ensure that the QCDR measures available for the performance period are meaningful and believe that the participation plan policy, as discussed in section III.K.3.g.(3)(c)(iii) of this final rule provides additional flexibility for low-reported QCDR measures that are currently under review for the 2020 performance period. If the QCDR measure is identified as an existing measure that is continuously low-reported, the QCDR has a chance to develop and submit a participation plan as a part of the QCDR measure reconsideration process.

Comment: One commenter requested additional clarity on the proposal to reject QCDR measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for two consecutive CY performance periods. The commenter requested clarification as to whether a measure would be rejected if it failed to meet benchmarking thresholds via one collection type but met thresholds via another.

Response: To clarify, QCDR measures are available through only a single collection type, a QCDR, and therefore, for purposes of the MIPS program a QCDR would only be submitting data on a QCDR measure only through a QCDR for purposes of MIPS reporting. However, if a QCDR has additional information or performance rate related information to share, utilizing data collected outside of the MIPS program, they may do so in the development of a participation plan as discussed above.

After consideration of the comments, we are finalizing § 414.1400 to add paragraph (b)(3)(iv)(J), as proposed, to state that, beginning with the 2020 performance period, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not meet this requirement, may not continue to be approved. We refer readers to section III.K.3.g.(3)(c)(ii) in the final rule, for discussion on how QCDRs may create participation plans for existing approved QCDR measures that have failed to reach benchmarking thresholds, in order to be reconsidered for future use.

(B) QCDR Measure Requirements

(aa) Previously Finalized Requirements Considerations Codified as Requirements

In the CY 2020 PFS proposed rule (84 FR 40815), we proposed to change two previously finalized measure considerations into requirements and codify those requirements. In the CY 2019 PFS final rule, we previously finalized that we would apply certain criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS (83 FR 59902). We refer readers to section III.K.3.g.(3)(c)(i)(A) of this final rule where we discuss our proposal to codify the majority as measure considerations (84 FR 40816). However, for two of those previously finalized considerations, in the CY 2020 PFS proposed rule, we proposed them as requirements (84 FR 40816):

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

We believe the previously finalized consideration that measures are beyond the measure concept phase of development should be a requirement because measures that do not surpass the measure concept phase will not be able to complete another QCDR measure requirement, measure testing. In addition, we believe the previously finalized consideration that measures address significant variation in performance should be a requirement because QCDR measures that do not demonstrate performance variation will likely be identified as topped out and will not be approved.

Therefore, beginning with the 2020 performance period, we proposed to change both of those considerations into requirements and proposed to amend § 414.1400 by adding § 414.1400(b)(3)(v) to include the following (84 FR 40816):

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposed requirements for a QCDR measure to be beyond the concept phase of development and address a significant variation in performance during the approval process.

Response: We thank the commenters for their support.

After consideration of the comments, we are finalizing our proposal as proposed, beginning with the 2020 performance period, to change both of the below listed considerations into requirements and add § 414.1400(b)(3)(v) to include the following for QCDR measure requirements for approval:

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

(bb) Linking QCDR Measures to Cost Measures, Improvement Activities, and MIPS Value Pathways (MVP)

To prepare QCDR measures for self-nomination, we believe there should be consideration of how these QCDR measures relate to similar topics covered through the other performance categories. We believe (as noted in the

CY 2020 PFS proposed rule (84 FR 40816)) that to transform the MIPS program to one of value, MIPS measures and QCDR measures, should have an associated cost measure, improvement activity, and eventually a corresponding MVP. This would strengthen the QCDR measure's relevance in the program. We believe that evaluating the strength of these linkages may decrease the frequency of receiving extraneous QCDR measures that are not relevant or meaningful within the framework of the MIPS program.

Therefore, in the CY 2020 PFS proposed rule, beginning with the 2021 performance period and future years, we proposed that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) Cost measure (as found in the CY 2020 PFS proposed rule (84 FR 40752 through 40762); (b) Improvement Activity (as found in Appendix 2: Improvement Activities Tables of the CY 2020 PFS proposed rule (84 FR 41275 through 41283)); or (c) CMS developed MVPs (as described in Table 34 of the CY 2020 PFS proposed rule (84 FR 40737 through 40738). Under the pathway framework for example, a surgery specific QCDR should be able to correlate their surgery-related QCDR measure to an MVP, such as the Major Surgery pathway.

We understand that not all measures may have a direct link. In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements defined above.

However, we believe that when possible, it is important to establish a strong linkage between quality, cost, and improvement activities. Therefore, we also proposed to amend § 414.1400 to add paragraph (b)(3)(iv)(G) to require, beginning with the 2021 performance period, that QCDRs link their QCDR measures to the following at the time of self-nomination: (a) Cost measure; (b) improvement activity; and (c) an MVP (84 FR 40816). If the potential QCDR measure otherwise meets the QCDR measure requirements but does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions for measures that otherwise meet the QCDR measure requirements and considerations as discussed above.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to require that QCDR measures be linked to cost measures, improvement activities, and MVPs. Several commenters supported an exception in cases where a QCDR measure lacks a clear link to either a cost measure, improvement activity, or MVP.

Response: We thank commenters for their support.

Comment: One commenter cited its belief that the proposal is not consistent with the regulatory language in that, the proposal states the linkage must be made to at least one of the categories while the regulatory language states the linkage must be made to all three. Another commenter stated that it is unclear whether the QCDR measure should be linked to at least one or all three of the performance categories. A few commenters sought clarification on the proposal to require QCDR measures be linked to cost measures, Improvement Activities, and MVPs, specifically whether QCDRs must link their measures to a cost measure, improvement activity, or a CMS-developed MVP, or all three; and how QCDRs will be required to identify linkages.

Response: In the CY 2020 PFS proposed rule (84 FR 40816), we stated that ''we believe that to transform the MIPS program to one of value, MIPS measures and QCDR measures, should have an associated cost measure, improvement activity, and eventually a corresponding MVP.'' In addition, we also stated, ''therefore, we also propose to amend § 414.1400 to add paragraph (b)(3)(iv)(G) to require, beginning with the 2021 performance period, that QCDRs link their QCDR measures as feasible to the following at the time of self-nomination: (a) Cost measure; (b) improvement activity; and (c) an MVP'' (84 FR 40816). However, we also proposed (84 FR 40816) that beginning with the 2021 performance period and future years, QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) Cost measure (as found in the CY 2020 PFS proposed rule (84 FR 40752 through 40762); (b) Improvement Activity (as found in Appendix 2: Improvement Activities Tables of the CY 2020 PFS proposed rule (84 FR 41275 through 41283)); or (c) CMS developed MVPs. We apologize for the confusion. We intended for the proposal to consistently use the term ''or,'' meaning that QCDRs would be required to link their measure to at least one performance category as feasible. Therefore, we are clarifying our requirement here in this final rule that QCDRs would not be required to link to all three performance categories at this time; but should try to link their measure to the performance categories as feasible.

Comment: A few commenters expressed concerns with the proposal to require QCDR measures to be linked with cost measures, improvement activities, and MIPS Value Pathways, noting that some specialties are not currently included in the cost category and/or MIPS Value Pathways and therefore, urged CMS to account for these types of clinicians by building flexibility into QCDR measure requirements. Other commenters noted linking to cost measures, improvement activities, and MIPS Value Pathways should be optional and not required.

Response: We appreciate the concerns raised by these commenters. We refer readers to our clarification above—QCDRs would be required to link their measure to at least one, not all three, performance category as feasible. In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or MVP, we proposed that we would consider exceptions if the potential QCDR measure otherwise met the QCDR measure requirements and considerations such as addressing a measurement gap. As stated in our proposal in the CY 2020 PFS proposed rule (84 FR 40926), in cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or MVP, we would consider exceptions if the potential QCDR measure otherwise met the QCDR measure requirements and considerations. If a QCDR measure cannot be linked to a cost measure because the specialty isn't reflected in the cost measures, then the QCDR would indicate there are no cost measures to link in their QCDR measure submission for us to note as a part of our review.

Comment: Several commenters stated that the method for linking QCDR measures is unclear as is the information required to explain the link. One commenter requested CMS provide additional education and guidance to QCDRs to assist them in adequately meeting the new requirement.

Response: As QCDRs consider which QCDR measures they want to submit for consideration, they should work to identify relationships that can link their QCDR measure to measures and activities in other performance categories. For example, a link can be established if the associated measures and activities address the same clinical condition or disease. We will require the QCDR to provide a narrative with their QCDR measure specification that

identifies the other measures and activities that relate, and explain why they believe there is a link. We agree that additional education and guidance would be beneficial. We plan to provide education to QCDRs to ensure that they adequately understand this requirement.

Comment: Several commenters disagreed with the proposal to require QCDR measures be linked to cost measures, improvement activities, and MIPS Value Pathways, citing their beliefs that: CMS should not implement any changes related to MIPS Value Pathways until the Agency has received and considered all comments related to the proposal and conducted outreach and meetings prior to the publication of next year's proposed rule (or alternatively a separate request for information (RFI) soliciting feedback). These commenters also expressed concern that continued development of new episode-based cost measures and MVPs may mean applicable measures and MVPs are not available at the time of self-nomination. One commenter noted that the effective date of this proposal is too soon and should be deferred until the MVP framework is established and measure developers have the necessary time to adapt to the new requirements and establish new measures to align with this new focus.

Response: This policy was proposed with a delayed implementation, to take into effect for the 2021 performance period, in order for QCDRs to get acclimated with developing linkages between QCDR measures and measures and activities found within other performance categories, as a way to prepare for MVPs. In the time between the proposed and final rule, we have conducted stakeholder outreach through listening sessions and public facing webinars, while also reviewing comments received as it related to MVPs. We believe the 2021 performance period is an appropriate timeframe because it coincides with the timing, since the MVP framework is being finalized in this final rule, in which the first set of MVPs will be developed for 2021. Furthermore, we note that this policy establishes linkages as feasible, therefore while it's preferable, it is not mandatory to link a QCDR measure to a future MVP. If an MVP is not available at the time of self-nomination, a QCDR should try to link their QCDR measure to a relevant cost measure and improvement activity as feasible.

After consideration of the comments, we are finalizing our proposal with clarification that QCDRs are required to link their measure to at least one performance category as feasible. Therefore, we are amending § 414.1400 to reflect this clarification and add paragraph (b)(3)(iv)(G) to require, beginning with the 2021 performance period, that QCDRs link their QCDR measures as feasible to at least one of the following at the time of self-nomination: (a) Cost measure; (b) improvement activity; or (c) an MVP. In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations as discussed above.

(cc) Completion of QCDR Measure Testing

We refer readers to the CY 2019 PFS final rule, where we gave notice to the public that we were considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking (83 FR 59901 through 59902). After consideration of the previous public comments received, and our priority to ensure that all measures available in MIPS are reliable and valid thereby reducing reporting burden on eligible clinicians and groups, we moved forward with a proposal in the CY 2020 PFS proposed rule (84 FR 40816).

Beginning with the 2021 performance period and future years, we proposed, that for a QCDR measure to be considered for use in the program, all QCDR measures submitted at the time of self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), and as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures (84 FR 40816 through 40817). We believe that full development and testing with completed testing results at the clinician level helps to demonstrate whether the QCDR measure is ready for implementation at the time of self-nomination. We intend to include only measures that are valid, reliable, and feasible for use by clinicians and will be consistent with the criteria that is expected of MIPS quality measures. As a result, we also proposed to amend § 414.1400 to add paragraph (b)(3)(v)(C) to reflect this proposal (84 FR 40817). At § 414.1400(b)(3)(v)(C), we proposed beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination (84 FR 40817).

We noted that the testing process for quality measures is dependent on the measure type (for example, a measure that is specified as an eCQM measure has additional steps it must undergo when compared to other measure types). The National Quality Forum (NQF) has developed guides for measure testing criteria and standards which further illustrate these differences based on measure type. Additionally, the costs associated with testing vary based on the complexity of the measure and the developing organization. The Journal of the American Medical Association states that the costs associated with quality measures are generally unknown or unreported.[118] While we understand the proposed policy will result in additional costs for QCDRs to develop measures, given the uncertainty regarding the number and types of measures that will be proposed in future performance periods coupled with the lack of available cost data on measure development and testing, we are unable to determine the financial impact of this proposal on QCDRs beyond the likelihood of it being more than trivial. Likewise, we understand that some QCDRs already perform measure testing prior to submission for approval while others do not. This variability makes it difficult to estimate the incremental impact of this regulation. Please refer to section VII., the Regulatory Impact Analysis, of this final rule for additional details.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposal to require measure testing prior to a QCDR measure being submitted for approval.

Response: We thank commenters for their support.

Comment: A few commenters requested clarification on the level of testing for which CMS is asking and whether it is full NQF-level specification and endorsement or a feasibility and validity test within the QCDR due to their opinion that NQF-level specification testing is both burdensome and expensive.

[118] Schuster, Onorato, and Meltzer. ''Measuring the Cost of Quality Measurement: A Missing Link in Quality Strategy'', Journal of the American Medical Association. 2017; 318(13):1219–1220. *https://jamanetwork.com/journals/jama/fullarticle/2653111?resultClick=1.*

Response: As stated in the CY 2020 PFS proposed rule (84 FR 40816 through 40817), we proposed that all QCDR measures submitted at the time of self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), and as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. As a reminder, we do not currently require QCDR measures to be NQF endorsed in order to be approved for use in the program. We believe in utilizing the existing NQF testing standard without variation, to avoid inconsistencies that may result from substandard results. We understand that measure testing requires an additional level of effort, cost, and time, but believe that measure testing ensures that measures are reliable, valid, and feasible. By completing this testing, QCDRs will avoid instances of discovering mid-year that their measure is not feasible or collectible, and will avoid adding to clinician reporting burden.

Comment: A commenter cited their opinion that should the proposal be finalized, CMS should provide leniency on following the CMS Blueprint for the CMS Measures Management System due to its belief that it was developed for use by measure contractors who presumably have dedicated resources, both in staffing and funding, to do the sole work of measure development, testing and maintenance; and that the measure development timeline and requirements as laid out in the Blueprint are aggressive, particularly for organizations dependent on limited funds and expert volunteers to complete the work.

Response: We disagree on providing leniency on testing requirements, as we expect to uphold the testing requirements that are utilized for MIPS quality measures through the CMS Blueprint for Measures Management System, and that the standard is upheld consistently for all QCDR measures and MIPS quality measures within the program. We believe QCDRs should research testing requirements for planning purposes from a timing and budget perspective. We will not consider measures that have incomplete testing results or those that do not meet the testing standards. Further the process outlined in the CMS Blueprint for the CMS Measures Management System is very thorough and following the Blueprint will substantially increase the scientific acceptability of the measure, and likelihood of the measure receiving endorsement. We note that while the Blueprint is required for CMS measure development contractors, it is a resource that can be used by any measure developer. We do recognize that resource availability in measure testing may vary, however, we reiterate the importance of following the Blueprint to produce a sound measure. Additionally, CMS provides support through webinars, resources, etc. through the Measure Management System: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Content-Page.html* For Measure Management System webinar sign-up we direct readers to email *MMSsupport@battelle.org.*

Comment: Many commenters disagreed with the proposal to require QCDR measures to have completed testing prior to nomination due to their beliefs that: It would delay the creation and submission of new measures by a number of months or even years; the process would be cost prohibitive for many QCDRs, especially those administered by non-profit medical societies; may result in some QCDRs electing to cease measure development or no longer participating in the MIPS program; could lead to increased licensing fees or participation fees for clinicians; and it removes the ability for clinicians to report on measures that are not in the CMS measure inventory.

Response: While we understand the increased time and cost burdens associated with measure testing, we believe the benefits of completed measure testing far outweigh the burdens of it. We want all measures available in the MIPS program to be reliable, feasible, valid, and implementable within the program. We want to avoid scenarios that would arise by allowing measures that do not meet these standards which then may lead to issues with the measure mid-performance period. We do not believe it is appropriate to have untested measures within the MIPS program since clinician's performance on measures have impacts on their payments. Furthermore, as we have signaled through previous rulemaking cycles (83 FR 59901 through 59902), we have intended to raise the bar for QCDR measures that are available for reporting within the MIPS program. We disagree that measure testing removes the ability for clinicians to report on measures that are not within the CMS inventory. To clarify, QCDRs can collect data on measures for purposes of quality improvement outside of the program, without reporting the data to CMS for purposes of MIPS.

Comment: Some commenters stated that this policy is contrary to Congress' initial intent for QCDRs to serve as testbeds for more robust and creative measures.

Response: We disagree with the commenter that this policy is contrary to Congress' intent for QCDRs as there is no reference in section 1848(q) of the Act to QCDRs serving as ''testbeds'' for more robust and creative measures.

Comment: A few commenters suggested testing measures during a trial period during which performance would not be counted against clinicians, and they may be offered some small incentive to report on the measures so that the developer can continue to refine them; or using interim testing results which could be collected while the measure is in use. One commenter expressed its belief that the proposal is unreasonable for smaller specialties or specialties where clinicians are more likely in small/solo practices due to the difficulty in operationalizing new measures and providing test data; and that the limited ability to use the Bonnie eCQM test deck also contributes to requiring large facilities with significant resources. This commenter also stated their belief that testing methodologies employed by academic medical centers could lack applicability and could cause measures commonly used by small/solo practitioners to fail external validity testing.

Response: We thank the commenters for their suggestions. We believe there is value and importance in ensuring the scientific rigor of measures through measure testing; and therefore, we will not accept trial testing in place of fully completed testing data at the clinician level. We understand there may be limitations with small specialties and the lack of resources to test measures, but believe it is important to only include measures that are valid, reliable, and feasible in the program. We want to ensure that the testing methodology used by all, including academic medical centers, in a consistent manner to ensure that results meet testing standards. In response to commenters on the limited ability to use the Bonnie eCQM test deck, we clarify that testing verifies the behavior of the eCQM logic. Bonnie tests the measure logic against the constructed patient test deck and evaluates whether the logic aligns with the intent of the measure. This is an element of the testing and is not full validity, reliability and feasibility testing. Bonnie is open source and free to use, so it is an available option for testing measure logic. We refer readers

to *https://bonnie.healthit.gov/* for additional information on Bonnie.

Comment: A few commenters expressed their opinion that since QCDRs may have access to real-world EHR data, it should be recognized by CMS as a means to achieve the goals of measure testing without having to test measures according to the methods outlined by NQF and the CMS measures blueprint. Finally, one commenter suggested that in place of this proposal, the proposal to require collection of 12 months of data prior to nominating a new QCDR measure could be used in its place.

Response: We disagree that having real-world access to EHR data is comparable to that of measure testing data or that requiring collection of 12 months of data on a QCDR measure could replace measure testing. Regardless of the QCDR measure's data source, all QCDR measures should be fully tested to ensure the measure is valid, reliable, and implementable at the clinician level. We clarify that the requirement to collect data on a QCDR measure prior to self-nominating is separate and apart from the requirement to fully test the measure. Data collection is meaningful because it demonstrates whether a measure is implementable and if there is interest by the clinician community on reporting on that metric.

Comment: One commenter stated that if the proposal if finalized, CMS should provide additional flexibility to their proposed timeframes for measures dealing with less common medical problems as it is often not feasible to measure rare surgical outcome events during the course of 1 year in a way that is statistically appropriate or reliable.

Response: We clarify that all QCDR measures, regardless of whether they have been approved for previous performance periods or are new QCDR measures will be expected to meet these new QCDR measures requirements and considerations to be approved for the 2021 performance period and future years. We will not be grandfathering in previously approved QCDR measures. To further clarify, we have not proposed timeframes for measure testing. As described in the CY 2020 PFS proposed rule (84 FR 40817), the testing process for quality measures is dependent on the measure type, for example, a measure that is specified as an eCQM measure has additional steps that it undergoes when compared to other measure types. We defer to QCDR measure owners as the experts in their specialty. We refer QDCRs to the Blueprint for the CMS Measures Management System (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*) for measure testing criteria and standards to determine timeframes that are appropriate for individual QCDR measure testing to ensure consistent and reliable standards are used. If a QCDR believes that they need more than 1 year is needed to ensure a measure is statistically appropriate, reliable, and to complete measure testing at the clinician level, then they should delay self-nominating the QCDR measure until testing is completed. Furthermore, we refer readers to the CY 2020 PFS proposed rule (84 FR 40818), where we proposed, and are finalizing in section III.K.3.g.(3)(c)(i) of this final rule, to reject QCDR measures that focus in on rare events or ''never events'' in the measurement period, and provided fires in the operating room as an example of a rare event.

After consideration of the comments, we are finalizing our proposals as proposed. Specifically, we are finalizing § 414.1400(b)(3)(v)(C), to state that beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. We are also finalizing our proposal that all QCDR measures submitted at the time of self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), and as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures.

(dd) Collection of Data on QCDR Measures

We have observed several instances in which QCDRs have attempted to use the MIPS Program to ''test'' out measure concepts without concrete evidence that there is a measurement performance gap. We want to discourage that and ensure QCDR measures used for the MIPS Program are valid and reliable. In addition, through reviews of QCDR measure submissions, where reporting data was provided by the QCDR or through submission data from the 2017 performance period, we have identified some current QCDR measures in the program that have continuously low reporting rates, which affects the ability to meet benchmarking criteria. The data submitted is insufficient in meeting the case minimum and volume thresholds required for benchmarking.

Therefore, in the CY 2020 PFS proposed rule, we proposed to require QCDRs to collect data on the potential QCDR measure (84 FR 40817). For a QCDR measure to be considered for use in the program, beginning with the 2021 performance period and future years, we proposed to amend § 414.1400 to add paragraph (b)(3)(v)(D) that QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period (84 FR 40817). The data collected must demonstrate whether the QCDR measure is valid and reflects an important clinical concept(s) that clinicians wish to be measured on. By collecting data on the QCDR measure prior to self-nomination, QCDRs would be able to demonstrate whether the measure is implementable and data collection on the metric is possible. In addition, the data collected on the QCDR measure prior to self-nomination, could be used to demonstrate that there is a performance gap and need for measurement. We suggest QCDRs to collect data on as many months as possible, but encourage QCDRs to collect data for 12 months prior to submitting the QCDR measure for our consideration at the time of self-nomination, since quality reporting requires 12 months of data, as described in § 414.1335, as this will also likely increase the chance that the measure will be able to be benchmarked.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter agreed with the proposal to require collection of data prior to submitting a QCDR measure for approval.

Response: We thank the commenter for their support.

Comment: One commenter advised CMS to delay implementation of this requirement for an additional year due to their belief that in order to meet this standard in 2021, QCDRs would need to begin immediately in 2020 to work on collection of this data, which may not be feasible given that budgets and timelines have already been planned for the year.

Response: We thank the commenter for their suggestion but disagree that there needs to be a delay in the implementation of this policy. We believe that implementing this requirement beginning with the 2021 performance period would allow for sufficient time needed for planning and

budgeting. We believe that this requirement to collect data on the measure prior to submitting it to CMS coincides with the need for data collection as a part of the measure testing process, and therefore, would believe that if a QCDR measure has completed testing as outlined in the CMS Blueprint *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf,* the QCDR would also be able to collect data on the measure to meet this requirement.

Comment: Several commenters disagreed with the proposal to require collection of data on QCDR measures prior to nomination due to their beliefs that it would unnecessarily delay the creation and submission of new measures, further challenging participation of specialists who have very few measures to report; would create additional burden and may cause some QCDRs to end participation in MIPS; and would require financial resources most specialty societies do not have. One commenter expressed its opinion that collection of data should not be a determinant of clinical importance as public comments may reveal importance and given that similar measures may be approved, clinicians may elect to report to one even when both are clinically important.

Response: We thank the commenters for raising these concerns. We believe that the benefits of this policy outweigh the burdens. While we understand that data collection may not be a determinant of clinical importance of a measure, data collection is important because it demonstrates whether a measure is implementable and if there is interest by the clinician community on reporting on that metric. We expect there to be a need for some data collection for testing purposes, as described in section III.K.3.g.(3)(c)(i)(B) of this final rule, and therefore, would believe that if a QCDR measure has completed testing as outlined in the CMS Blueprint, the QCDR measure would also be able to meet this requirement.

Comment: One commenter suggested that in place of the proposal, QCDR measures could be approved under a testing/provisional status during which CMS would allow credit, such as a base 3–5 points or fully meeting improvement activity requirements.

Response: We disagree with the commenter's suggestion of giving QCDR measures provisional approval prior to meeting this requirement. We want all measures available in the MIPS program to be reliable, feasible, and valid, and implementable within the program. We do not believe QCDRs should be using the MIPS program as a test-bed for measure development, particularly since this is a pay-for-performance program and clinician's performance on measures have impacts on their payments.

Comment: One commenter stated that CMS should not penalize a QCDR for providing data for a period of less than 12 months for QCDR measures as collecting data for a 12-month period may be difficult given that the timelines of the MIPS submission cycle during the months of January–March, the requirement for QCDRs to be operational on January 1, and the self-nomination deadlines September 1; around which the QCDR's measure development and update processes have been established.

Response: To clarify, as described in the CY 2020 PFS proposed rule (84 FR 40817), we suggest QCDRs to collect data on as many months as possible, but encourage QCDRs to collect data for 12 months prior to submitting the QCDR measure for our consideration at the time of self-nomination. While we encourage 12 months of data, we do understand there may be instances where less than 12 months of data may be available, depending on the data available as a result of measure testing or the availability of the QCDR measure during past performance periods in MIPS.

After consideration of the comments, we are finalizing our proposals as proposed. Specifically, we are requiring QCDRs to collect data on potential QCDR measures. Beginning with the 2021 performance period and future years, for a QCDR measure to be considered for use in the program, we are adding § 414.1400 (b)(3)(v)(D) to state that QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. The data collected must demonstrate whether the QCDR measure is valid and reflects an important clinical concept(s) that clinicians wish to be measured on.

(ee) Duplicative QCDR Measures

As first discussed by commenters in the CY 2018 Quality Payment Program final rule (82 FR 53814), the topic of ''shared'' measures was discussed and how would CMS intend to harmonize. In the CY 2019 PFS proposed rule (83 FR 35983), and further discussed in CY 2019 PFS final rule (83 FR 59901), we shared that we believe duplicative measures are counterintuitive to the Meaningful Measures initiative that promotes more focused quality measure development towards outcomes that are meaningful to patients, families and their providers. Therefore, it is our intent to move toward measure harmonization, which supports our efforts to increase measure alignment and eliminate redundancy both within the MIPS measure set and across our programs (83 FR 59901). Taking the previous feedback into consideration, we moved forward with a proposal in the CY 2020 PFS proposed rule (84 FR 40817).

In the CY 2020 PFS proposed rule (84 FR 40817), we proposed, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. In other words, we would not approve duplicative QCDR measures (which will be identified as a part of our scan of previously approved measures, and new QCDR measure submissions) if QCDRs choose not to address the areas of duplication with other approved QCDR measures identified by us during the previous year's QCDR measure review period. We believe this policy would help to reduce the number of duplicative QCDR measures that are submitted as a part of the self-nomination process. Adding a structured timeframe provides transparency to QCDRs who will know what next steps to expect if they do not address the identified areas of duplication as requested. Therefore, we proposed to amend § 414.1400 to add paragraph (b)(3)(v)(E) to state beginning with the 2022 MIPS payment year (2020 performance period), CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other

approved QCDR measures in order to be considered for the program in subsequent years (84 FR 40818). If the QCDR measures are not harmonized, CMS may reject the duplicative QCDR measure(s) as discussed in the CY 2020 PFS proposed rule (84 FR 40818).

We received public comments on these proposals. We acknowledge that we received several comments that were out of scope for this final rule, which we are not addressing in this rule, but thank commenters for the feedback. The following is a summary of the in-scope comments we received and our responses.

Comment: One commenter expressed its opinion that allowing duplicative measure concepts to go forward in the MIPS program fosters confusion among clinicians and competition among QCDRs, rather than collaboration; and that organizations will not be able to continue to invest in advancing meaningful quality measures if their measure concepts are able to be appropriated with superficial changes and then supported by CMS.

Response: We agree with the commenter's concerns on duplicative measures creating confusion for clinicians. However, we note that we have continuously encouraged QCDRs to collaborate to develop cohesive, robust QCDR measures through the use of QCDR measure informal group discussions, reminders on monthly support calls and at QCDR measure preview calls. We have come across instances where QCDRs have refused to collaborate with one another, exacerbating the issue of competition rather than mitigating it.

To clarify, as a part of the QCDR measure review process, we review all new QCDR measures submitted at the time of self-nomination and compare the new measures to previously approved QCDR measures. In instances where there are no significant differences, for example, in patient population or quality action, and the specification of the new measure is duplicate of an existing measure, we would reject the new measure and recommend the QCDR to seek permission to use the existing approved QCDR measure. In instances where there is overlap, and both measures cover a similar clinical concept, but with differing quality actions or patient populations, we will request measure harmonization. In instances where QCDRs cannot or refuse to collaborate to harmonize their measures, we will select and approve the most robust QCDR measure and reject any duplicative ones.

Comment: Some commenters requested additional clarification and guidance should the proposal be finalized. Some commenters stated that CMS should provide clear guidance when and how measures should be harmonized in order to ensure that contractor decisions are as uniform as possible Other commenters requested timelines for making changes or harmonizing measures, what safeguards will be implemented to ensure harmonization will only occur when clinically appropriate; and accountability of QCDRs that do not have appropriate experience or expertise in the field of medicine covered by the measure.

Response: We agree that clear guidance should be communicated to QCDRs who have been identified to collaborate on harmonization efforts. After the close of the self-nomination period, we will review QCDR self-nomination applications. As a part of this measure review process, we will identify similar QCDR measures for harmonization and then notify the relevant QCDRs through the Self-Nomination Portal that their QCDR measures have been identified for measure harmonization. In this communication, we will include our reasons as to why we believe harmonization is appropriate, including where we believe duplication exists, points of contact from the other identified QCDRs, and information regarding provisional approval for the given year. As proposed in the CY 2020 PFS proposed rule (84 FR 40818), we specified that we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures within that year, prior to the next self-nomination period. With regards to ensuring that harmonization will only occur when clinically appropriate, we do review clinical appropriateness when requesting harmonization; however, we rely on the QCDRs to indicate, as a part of their QCDR measure reconsideration, when and why they believe harmonization is not appropriate. The additional information provided may be used to reconsider whether the QCDR measure should be harmonized or not.

Comment: Several commenters cited their belief that CMS should grant 2 years of provisional approval instead of 1.

Response: We disagree that a 2-year provisional approval cycle should be granted in these scenarios, as we believe it is important not to prolong measure harmonization. We understand that measure harmonization takes time for there to be agreement amongst the QCDRs and their technical expert panels. However, we believe it is counterintuitive to the Meaningful Measure Initiative to prolong retaining duplicative measures in the program.

Comment: A few commenters stated their concerns over the process CMS will utilize to determine which QCDR measures are duplicative. Some commenters stated that CMS clarify the criteria for determinations that QCDR measures are duplicative. A few commenters encouraged CMS to: Consider the level of rigor in evidence or testing process between QCDRs; make determinations based on a comparison of the technical specifications; consider that an existing measure with baseline performance should not be rejected in favor of a new measure without prior data collection or baseline performance; consider a QCDR's relevant expertise or experience in the specialty or treatment area covered by a particular measure should be given. One commenter stated that if CMS identifies a measure that needs to be harmonized, CMS should provide the clinical rationale for harmonization. Another commenter stated that CMS and their contractors should consult with clinicians and measurement staff in the specialty societies regarding clinical aspects of measurement.

Response: We thank the commenters for raising these concerns. As a part of the review process, QCDR measure specifications are comparatively reviewed for similarities and differences when they address the same clinical topic. QCDR measures are considered duplicative if there are no differences between the measure specifications from a comparative perspective. To clarify, in instances where a new QCDR measure is duplicative of an existing QCDR measure, we would reject the new duplicative QCDR measure and tell the QCDR to request permission to use the existing QCDR measure. We would request measure harmonization in instances where QCDR measures are identified as similar. QCDR measures are reviewed to identify similarities and differences in areas that include (but are not limited to): Clinical concept being measured, quality action (for example, screening versus screening and follow-up), patient population, clinical setting (place of service), and the clinician type eligible to report on the measure. We thank the commenters for their suggestions of what CMS should consider, but note that for the 2020 performance period and in previous years, we have not previously required measure testing, and it would, therefore,

be difficult to evaluate all QCDR measures with this criteria, if it is not consistently required. With regards to the suggestion that an existing measure with baseline performance should not be rejected in favor of a new measure without prior data collection or baseline performance, we believe that the data collection requirement for QCDR measures, beginning with the 2021 performance period will mitigate this concern. However, this would not be the only reason we would select an existing measure over a new QCDR measure. While some consideration would be given to an existing measure, there have been instances where a similar measure with a more vigorous (or robust) quality action had been submitted for consideration. In instances where we are able to identify strong qualities in both similar measures, we ask for measure harmonization. In instances, where one measure completely overlaps another's clinical concept but includes a more robust quality action, our preference would be to select the more robust QCDR measure (regardless of a given QCDR measure's history within the program). We expect QCDRs to be nimble and innovative and work collaboratively and independently to develop inventive measures that go beyond standard-of-care, process measures. A QCDR's relevant expertise in the specialty is given some consideration, but would not be the deciding factor as several QCDRs may have overlapping expertise. In instances in which a QCDR has simply duplicated another existing approved QCDR measure without modification, we would not approve the newly duplicated QCDR measure. Furthermore, we appreciate the commenter's suggestion that we consult with clinicians and measurement staff in the specialty societies regarding clinical aspects of measurement. We want to note that QCDR measures are reviewed by staff and contractors who have various clinical backgrounds and experience with quality measures, including input from physicians on CMS staff and on our contracting team. There may be instances where the QCDR is affiliated with a specialty society, but this is not always the case. We would expect that QCDRs would develop QCDR measures reflective of their area of clinical experience and strength, and continuously engage in discussions with the QCDRs regarding the clinical aspects of their QCDR measures through QCDR measure preview calls and QCDR measure reconsideration calls. It is at these meetings where QCDRs are given the opportunity to present and rationalize the need for quality metrics around the topic at hand. We disagree that specialty societies should be involved in evaluating QCDR measures for which they are not the owners of, while we understand they may be experts in their respected field, we believe conflicts of interest may arise when the specialty society themselves have their own QCDR and are then allowed to evaluate QCDR measures from another QCDR of the same specialty.

Comment: A few commenters stated that CMS should not encourage harmonization in cases where one QCDR is effectively trying to use another QCDR's measure without license or compensation.

Response: In instances in which a QCDR has simply duplicated another existing approved QCDR measure without modification, we would not request harmonization or approve the newly duplicated QCDR measure. The QCDR will be requested to seek permission from the QCDR who owns the previously approved QCDR measure. Ultimately, any concerns with infringement of intellectual property of QCDR measures between QCDRs will be left between the QCDRs to mitigate and resolve.

Comment: A few commenters disagreed with CMS' encouragement of harmonization due to their belief that the process of achieving harmonization is difficult ''when one QCDR may own the changes and carry them out while another QCDR may act as the measure steward.'' One commenter asserted that harmonization places undue burden to reporting clinicians and eliminates the flexibility that had been originally built into QCDR measure reporting.

Response: We thank the commenter for raising these concerns. In our view, QCDR measures that are not harmonized place undue burden on reporting clinicians and eliminates flexibility. The brunt of the responsibility falls to QCDRs to resolve duplication and harmonization efforts to submit a consolidated QCDR measure. We believe measure harmonization is consistent with the Meaningful Measure Initiative. The purpose of measure harmonization is to reduce and consolidate the number of duplicative or similar measures within the program, which would result in a larger cohort of clinicians reporting on a consolidated measure. We believe this would improve the likelihood that newly harmonized measures will be able to reach benchmarking thresholds. We expect that if QCDRs are unable to determine roles and responsibilities as it pertains to measure harmonization efforts, they would inform CMS; we would use such information to help determine whether the most robust measure should instead just be selected.

After consideration of the comments, we are finalizing our proposals as proposed. Specifically, beginning with the 2020 performance period, we are finalizing that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). We are also finalizing our proposal to amend § 414.1400 to add paragraph (b)(3)(v)(E) to state that beginning with the 2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. If the QCDR measures are not harmonized, CMS may reject the duplicative QCDR measure(s) as discussed in section III.K.3.g.(3)(c)(i)(C) of this final rule.

(C) QCDR Measure Rejections

In the CY 2020 PFS proposed rule (84 FR 40818), we proposed QCDR measure rejection criteria that generally align with finalized removal criteria for MIPS quality measures in the CY 2019 PFS final rule (83 FR 59763 through 59765). Utilizing these considerations would help to ensure that QCDR measures available in the program are truly meaningful and measurable areas where quality improvement is sought. As part of the proposal (84 FR 40818), all previously approved QCDR measures and new QCDR measures would be reviewed on an annual basis (as a part of the QCDR measure review process that occurs after the self-nomination period closes on September 1st) to determine whether they are appropriate for the program.

We proposed to amend § 414.1400 to add paragraph (b)(3)(vii) to state that beginning with the 2020 performance period, QCDR measure rejection criteria, include, but are not limited to, the following factors (84 FR 40818):

- QCDR measures that are duplicative or identical to other QCDR measures or MIPS quality measures that are currently in the program.
- QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.
- QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality

Reporting System (PQRS) program, which have been retired.

• QCDR measures that meet the ''topped out'' definition as described at § 414.1305 and in the CY 2017 Quality Payment Program final rule (81 FR 77282 through 77283). If a QCDR measure is topped out and rejected, it may be reconsidered for the program in future years if the QCDR can provide evidence through additional data and/or recent literature that a performance gap exists and show that the measure is no longer topped out during the next QCDR measure self-nomination process.

• QCDR measures that are process-based, with considerations to whether the removal of the process measure impacts the number of measures available for a specific specialty.

• Whether the QCDR measure has potential unintended consequences to a patient's care. For example, the measure disqualifies a patient from receiving oxygen therapy or other comfort measures.

• Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.

• Whether the previously identified areas of duplication have been addressed as requested. (We refer readers to our proposal discussed in section III.K.3.g.(3)(c)(i)(B) of the CY 2020 PFS proposed rule (84 FR 40816).)

• QCDR measures that split a single clinical practice or action into several QCDR measures. For example, splitting a measure into multiple measures based on a particular body extremity: Improvement in toe pain—the 5th toe, and a separate measure for the 2nd toe.

• QCDR measures that are ''check-box'' with no actionable quality action. For example, a QCDR measure that measures that a survey has been distributed to patients.

• QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years (we also refer readers to our proposal in section III.K.3.g.(3)(c)(ii) of the proposed rule (84 FR 40818).

• Whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality action, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.

• QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician. (That is, the quality aspect being measured cannot be attributed to the clinician or is not under the direct control of the reporting clinician).

• QCDR measures that focus on rare events or ''never events'' in the measurement period. An example of a ''never event'' would be a fire in the operating room.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposed QCDR measure rejection criteria, specifically noting that the criteria make QCDRs a more comprehensive solution for providers and allow them to better leverage the data they are collecting.

Response: We thank commenters for their support.

Comment: A few commenters urged CMS to consider the limited number of measures available to non-patient facing clinicians when evaluating process-based measures.

Response: As a part of our QCDR measure considerations, we will take into consideration the availability of measures for a given specialty, particularly those for non-patient facing clinicians. While our general preference is to have more outcome measures in the program, we do understand a need for process measures, particularly for non-patient facing clinicians. Non-patient facing clinicians are limited in the availability of outcome measures that are available and measurable within their practice. Therefore, in instances where the outcome related metrics are limited or topping out, we encourage non-patient facing specialties to develop measures that address a high priority area (such as patient experience or care coordination) when it is not feasible to develop outcome measures.

Comment: One commenter disagreed with what they believe is the routine removal of QCDR process measures without regard to their relationship to outcome, impact on safety, demonstrated gap in practice, or the duration of time before an outcome measure exists or before outcome data are available. The commenter further noted that process measures should not be rejected if QCDR data proves that they improve outcomes and they are not topped out, as process measures require considerable work, are not ''check box'' measures, are difficult to perform, and target a demonstrated gap in practice.

Response: While our general preference is to have more outcome measures in the program, we do understand a need for process measures, particularly for non-patient facing clinicians. We would encourage specialties to develop measures that address a high priority area when it is not feasible to develop outcome measures. In addition, we will take into consideration performance gap information that is provided by a QCDR that demonstrates a process measure is not topped out. As a part of the QCDR measure review process, we do take into consideration any concerns with safety, any gap information a QCDR can provide to demonstrate one exists. We note that while we generally prefer outcome measures, and would like to move away from process measures in the program, we understand the time it takes to develop outcome measures. We consider ''check box'' measures, as measures that we have observed to be low-bar process measures that require a limited quality action that top out fairly quickly within the MIPS program and in our legacy PQRS program. If QCDRs are able to demonstrate a gap in practice for their process measure that information will be considered as a part of the QCDR measure approval process. In instances where QCDRs may disagree with their QCDR measure rejection, they may request a reconsideration call to discuss their position with CMS.

Comment: One commenter disagreed with the following rejection criteria: ''QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician. (That is, the quality aspect being measured cannot be attributed to the clinician or is not under the direct control of the reporting clinician)''. The commenter believed that it is often the case that a quality action is not in a clinician's direct control, but that does mean the clinician should not take responsibility for ensuring high quality of care; another words in instances when the measure is not directly attributable to the clinician, the clinician should not be held responsible for the quality of care. The commenter further cited their belief that this criterion is contrary to CMS' overarching goal of promoting and rewarding coordinated care.

Response: We understand the importance of care coordination, but we also believe it is important that clinicians and groups are not inadvertently penalized for actions that are outside of their control. We understand that clinicians may not always have direct control of the quality action taking place, and that there are instances where care utilizes a team-based approach. We have discussed our concerns regarding attribution and holding an individual clinician responsible for the results of a team-based approach with QCDRs during

some of their QCDR measure reconsideration calls, and they have clarified that in some specialties, this is the approach they choose to use to provide high quality care. Many patient outcomes are multi-factorial and can be influenced by the actions of multiple clinicians, even if none of them control it directly. After the QCDR measure self-nomination period, as part of our measure review process, we review clinician attribution criteria. As part of the QDCR measure nomination, for measures that do not have a clear clinician attribution, we encourage QCDRs to submit a short explanation. We continue to be open to having discussions with QCDRs as they develop QCDR measures to understand the way in which they have attributed a measure. We do note that we will expect that QCDRs will provide evidence that shows that their attribution methodologies are valid, and will note that we will ultimately decide the QCDR measures approval status on a case-by-case basis.

Comment: One commenter expressed concern that the term ''robust'' is not clearly defined as part of the rejection criteria: ''whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality action, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization''.

Response: A robust measure refers to measures with the most vigorous quality action or guidance or as a descriptor to describe strong, vigorous, or thoroughly vetted components of a measure. We also refer readers to the CMS Blueprint where we have similarly defined ''robust'': *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

Comment: A few commenters disagreed with the policy for rejecting topped-out QCDR measures due to their beliefs that CMS is limiting the number of specialty-specific measures available in the MIPS program by not providing QCDRs a grace period to phase out measures; and that CMS should allow QCDR measure developers to re-tool measures removed from the program into specialty or procedure-specific measures. One commenter expressed its belief that allowing QCDR measures to be phased out over more than a 1-year period will give measure owners time to appropriately phase out the measure, and determine what subsequent action to take, such as retiring the measure, modifying the measure to make it more robust, or creating a complementary measure. Another commenter requested that CMS publicly report measure data stratified by specialty, as well as practice size and type, prior to removing a measure due to it being topped out.

Response: We thank the commenter for their input but note that we do not see the need for a grace period to phase out QCDR measures. It is not consistent with the Meaningful Measures Initiative to retain topped out QCDR measures in the program when there are other relevant measures available for a given specialty. As a part of the review process, consideration is given to the number of measures remaining for a given specialty, whether there are additional specialty related measures in other QCDRs, and considerations to the MIPS quality measures inventory prior to rejecting a QCDR measure. In addition, QCDRs are expected to be nimble and innovative to work collaboratively and independently to develop inventive measures, which go beyond standard-of-care, process measures, that are often considered low-bar. We anticipate that QCDRs monitor the progress of their QCDR measures throughout the performance period, as well as year-over-year, and through their innovation, will work to submit new QCDR measures in future self-nomination periods. As a part of our QCDR measure removal process, we do give consideration to the availability of other specialty-specific measures, particularly outcome or high priority measures, available in the MIPS program prior to flagging any given measure for removal. In addition, performance data provided in the QCDR measure self-nomination demonstrating that a performance gap still exists will be taken into consideration prior to a final decision.

Comment: One commenter stated its opinion that a topped out measure should not be retired without having an alternative measure in place.

Response: As a part of the measure removal process, we typically evaluate the availability of measures to a given specialty as a part of the removal process. QCDRs are expected to be innovative in their development, and we believe since they can support QCDR and MIPS quality measures, there should be a sufficient number of measures left for a given specialty.

After consideration of the comments, we are finalizing our proposals as proposed. Specifically, we are finalizing that all previously approved QCDR measures and new QCDR measures would be reviewed on an annual basis (as a part of the QCDR measure review process that occurs after the self-nomination period closes on September 1st) to determine whether they are appropriate for the program. We are also amending § 414.1400 to add paragraph (b)(3)(vii) to state that beginning with the 2020 performance period, we will reject QCDR measures with consideration of, but not limited to, the following factors:

- QCDR measures that are duplicative or identical to other QCDR measures or MIPS quality measures that are currently in the program.
- QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.
- QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.
- QCDR measures that meet the ''topped out'' definition as described at § 414.1305 and in the CY 2017 Quality Payment Program final rule (81 FR 77282 through 77283). If a QCDR measure is topped out and rejected, it may be reconsidered for the program in future years if the QCDR can provide evidence through additional data and/or recent literature that a performance gap exists and show that the measure is no longer topped out during the next QCDR measure self-nomination process.
- QCDR measures that are process-based, with considerations to whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the QCDR measure has potential unintended consequences to a patient's care. For example, the measure disqualifies a patient from receiving oxygen therapy or other comfort measures.
- Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.
- Whether the previously identified areas of duplication have been addressed as requested. (We refer readers to our proposal discussed in section III.K.3.g.(3)(c)(i)(B) of this final rule.)
- QCDR measures that split a single clinical practice or action into several QCDR measures. For example, splitting a measure into multiple measures based on a particular body extremity: Improvement in toe pain- the 5th toe, and a separate measure for the 2nd toe.
- QCDR measures that are ''check-box'' with no actionable quality action. For example, a QCDR measure that measures that a survey has been distributed to patients.
- QCDR measures that do not meet the case minimum and reporting

volumes required for benchmarking after being in the program for 2 consecutive years (we also refer readers to our proposal in section III.K.3.g.(3)(c)(ii) of this final rule).

- Whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality action, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.
- QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician. (That is, the quality aspect being measured cannot be attributed to the clinician or is not under the direct control of the reporting clinician).
- QCDR measures that focus on rare events or ''never events'' in the measurement period. An example of a ''never event'' would be a fire in the operating room.

(ii) QCDR Measure Review Process

(A) Current QCDR Measure Approval Process

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), and the CY 2019 PFS final rule (83 FR 59900 through 59906), and § 414.1400(b)(3) for our previously established policies for the QCDR measure self-nomination process. QCDR measures are reviewed for inclusion on an annual basis during the QCDR measure review process that occurs once the self-nomination period closes (82 FR 53810). All previously approved QCDR measures and new QCDR measures are currently reviewed on an annual basis to determine whether they are appropriate for the program (82 FR 53811). The QCDR measure review process occurs after the self-nomination period closes on September 1st. QCDR measures are not finalized or removed through notice and comment rulemaking; instead, they are currently approved or not approved through a subregulatory processes (82 FR 53639). While we would continue to review measures on an annual basis, in the CY 2020 PFS proposed rule, we proposed the addition of a multi-year approval process (84 FR 40818).

(B) Multi-Year QCDR Measure Approval

Previously in the CY 2018 Quality Payment Program final rule (82 FR 53808), we discussed our concerns with multi-year approval for QCDR measures and sought comment from stakeholders as to how to mitigate our concerns. Based on the evolution of public comments in the CY 2019 PFS final rule (83 FR 59898 through 59901) and ongoing engagement with QCDRs, we are made a proposal in the CY 2020 PFS proposed rule (84 FR 40818).

Currently, our QCDR measure approvals are on a year-to-year basis (82 FR 53811), from September to December once self-nomination occurs. In addition to that process, to help reduce yearly self-nomination burden and address stakeholder feedback (83 FR 59898 through 59901), in the CY 2020 PFS proposed rule (84 FR 40818), we proposed to amend § 414.1400 to add paragraph (b)(3)(vi) to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described above.

However, as proposed, upon annual review, we may revoke the second year's approval if a QCDR measure approved for 2 years is (84 FR 40818 through 40819):

- Topped out (we refer readers to § 414.1305, in the CY 2017 Quality Payment Program final rule (81 FR 77282 through 77283));
- Duplicative of a more robust measure (this proposal aligns with our proposal at section III.K.3.g.(3)(c) in the proposed rule (84 FR 40814 through 40819);
- Reflects an outdated clinical guideline;
- Requires measure harmonization (this proposal aligns with our proposal at section III.K.3.g.(3)(c)(i)(B) in the proposed rule (84 FR 40816)); or
- The QCDR self-nominating the QCDR measure is no longer in good standing, as described in the CY 2018 Quality Payment Program final rule (82 FR 53808).

We believe that this policy should be an incentive for QCDRs who have remained in good standing in the program. Additionally, for QCDRs not in good standing, we want to make clear that we would not remove a measure mid-year; rather, the measure's 2-year approval would be revoked during annual review after 1 year and the QCDR's measures would no longer qualify for multi-year approval in the future. For example, if QCDR ABC is placed on probation in July, all of the QCDR's measures still would be available for reporting for that performance period (until December 31st); however, if any of QCDR ABC's QCDR measures were previously approved for 2 years, the approval would be revoked for the second year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to approve QCDR measures for multiple years due to their beliefs that approving measures for multiple years and posting updated specifications by November 1 would: Allow individuals and groups a better opportunity to meet the proposed 70 percent data completeness threshold; allow sufficient time for measure implementation, data collection for the next year's self-nomination, and improvement opportunities for practices; provide stability to MIPS; reduce burden; and allow for additional resources to be utilized for development of new measures.

Response: We thank commenters for their support.

Comment: A few commenters stated that QCDR measures should be approved for 2 years without being subject to CMS discretion as long as the measure satisfies QCDR measure requirements.

Response: We believe a 2-year approval should be left to our discretion, because many considerations must be given: QCDR's ability to comply with program requirements, considerations to other QCDR measures with more robust quality actions, future changes to program requirements, and in consideration of future transitions to MVPs.

After consideration of the comments, we are finalizing our proposals as proposed. Specifically, we are amending § 414.1400 to add paragraph (b)(3)(vi) to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described above. However, upon annual review, we may revoke the second year's approval if a QCDR measure approved for 2 years is:

- Topped out (we refer readers to § 414.1305, in the CY 2017 Quality Payment Program final rule (81 FR 77282 through 77283));
- Duplicative of a more robust measure (this proposal aligns with our proposal at section III.K.3.g.(3)(c) in this final rule);
- Reflects an outdated clinical guideline;
- Requires measure harmonization (this proposal aligns with our proposal at section III.K.3.g.(3)(c)(i)(B) in this final rule); or
- The QCDR self-nominating the QCDR measure is no longer in good

standing, as described in the CY 2018 Quality Payment Program final rule (82 FR 53808).

(iii) Participation Plan for Existing QCDR Measures That Have Failed To Reach Benchmarking Thresholds

We refer readers to the CY 2020 PFS proposed rule for discussion of the consideration of QCDR measures that fail to meet benchmarking thresholds after being in the program for 2 consecutive CY performance may not continue to be approved in the future (84 FR 40814 through 40818).

However, we understand that there are instances where measures that are low-reported may still be considered important to a respective specialty. Therefore, in the CY 2020 PFS proposed rule (84 FR 40819), beginning with the 2020 performance period, we proposed to amend § 414.1400 to add paragraph (b)(3)(iv)(J)(*1*) to state that in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration (84 FR 40819). This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program. As examples, a QCDR measure participation plan could include one or more of the following:

- Development of an education and communication plan.
- Update the QCDR measure's specification with changes to encourage broader participation, which would require review and approval by us.
- Require reporting on the QCDR measure as a condition of reporting through the QCDR.

To be clear, implementation of a participation plan would not guarantee that a QCDR measure would be approved for a future performance period, as we consider many factors in whether to approve QCDR measures. At the following annual review of QCDR measures, we would analyze the measure's data submissions to determine whether the QCDR measure participation plan was effective (meaning, reporting volume increased, thereby increasing the likelihood of the QCDR measure being benchmarked). If the data does not show an increase in reporting volume, we may not approve the QCDR measure for the subsequent year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposal to allow QCDRs to submit measure participation plans for QCDR measures that have failed to meet benchmarking thresholds and urge CMS to leave open a mechanism for the retention of measures that are important to small segments of reporting clinicians, even if those measures fail to reach a benchmark, as this is very critical to ensuring that important measures are not removed from the program due to scoring methodologies and preferences, and to encourage reporting on high value measures.

Response: We thank the commenters for their support.

Comment: One commenter requested that CMS specify in the final rule when notice of low reporting volume will be given so that QCDRs may have ample time to develop and implement the participation plan.

Response: QCDRs should be monitoring the reporting of their QCDR measures throughout the year and should be able to identify when their measures are low-reported. In addition, existing QCDR measures who have reached benchmarking thresholds would be included in the Quality benchmarking file that is posted annually in the Quality Payment Program Resource Library.

After consideration of the comments, we are finalizing our proposals as proposed. Specifically, beginning with the 2020 performance period, we are amending § 414.1400 to add paragraph (b)(3)(iv)(J)(*1*) to state in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.

(4) Qualified Registries

We refer readers to §§ 414.1305 and 414.1400, the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818) and the CY 2019 PFS final rule proposed rule (83 FR 59906) for our previously finalized policies regarding qualified registries. In the CY 2020 PFS proposed rule (84 FR 40819), we proposed to update qualified registry required services. These proposed policies would also affect the qualified registry self-nomination process.

(a) Qualified Registry Required Services

(i) Requirement for Qualified Registries To Support All Three Performance Categories Where Data Submission Is Required

We refer readers to section 1848(k)(4) of the Act for statutory authority. We also refer readers to section III.K.3.g.(1) in this final rule, where we discuss our proposal to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability (84 FR 40811). In addition, we refer readers to section III.K.3.g.(3)(a)(i) of this final rule where we discuss a parallel requirement for QCDRs (84 FR 40812 through 40813). In this section, we discuss qualified registries specifically. Based on previously finalized policies the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at (83 FR 60088) and § 414.1400(a)(2), the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability.

We want to continue to strengthen our policies at § 414.1400(a)(2). Based on our review of existing 2019 qualified registries, approximately 95 qualified registries, or about 70 percent of the qualified registries currently participating in the program are supporting all three performance categories. While we do not yet have data to share for how clinicians participated in 2019 (year 3), we do want to indicate that we have observed from 2017 (year 1) to 2018 (year 2) approximately 24 percent increasing to 36 percent of clinicians have used their QCDR/qualified registry for submitting for all 3 performance categories. We believe when this policy becomes finalized, more MIPS eligible clinicians may want to use this method as a burden reduction on data submission. When the CY 2020 PFS proposed rule was published the 2019 Qualified Registries Qualified Posting was available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/348/2019%20Qualified%20Registry%20Posting_Final_v1.0.xlsx* (84 FR 40819). Since the publication of that proposed rule, the link has since been updated and is now available on the Quality Payment Program resource library at *https://qpp.cms.gov/about/resource-library* by searching ''2019 Qualified Registries Qualified Posting.''

We believe it is reasonable that all qualified registries have the capacity to support the improvement activities and promoting interoperability performance categories.

We believe that requiring qualified registries to be able to support these performance categories will be a step towards addressing stakeholders concerns on having a more cohesive participation experience across all performance categories under MIPS. In addition, we believe this proposal will help to reduce the reporting burden MIPS eligible clinicians and groups face when having to utilize multiple submission mechanisms to meet the reporting requirements of the various performance categories. Furthermore, as we move to a more cohesive participation experience under the MVPs, as discussed in the CY 2020 PFS proposed rule (84 FR 40732 through 40745), we believe this proposal will assist clinicians in that transition. We also refer readers to section III.K.3.a. of this final rule where the MIPS MVP is discussed.

Therefore, as discussed in the CY 2020 PFS proposed rule (84 FR 40819), beginning with the 2023 MIPS payment year (2021 performance period) and for future years, we proposed at § 414.1400(a)(2) to require qualified registries to support all three performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability with an exception. As discussed in the CY 2020 PFS proposed rule (84 FR 40819), we proposed that based on the amendment to § 414.1400(a)(2)(iii), to state that for the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4), (c)(2)(i)(A)(5), (c)(2)(i)(C)(1) through (c)(2)(i)(C)(7), or (c)(2)(i)(C)(*9*). As part of this proposal, we will (84 FR 40819 through 40821) require qualified registries to attest to the ability to submit data for these performance categories, as applicable, at time of self-nomination. We also proposed this same requirement for QCDRs in section III.K.3.g.(3) of the CY 2020 PFS proposed rule (84 FR 40813) and refer readers to section III.K.3.g.(3) of this final rule for a discussion.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposal to require qualified registries to support the reporting of data for the quality, Promoting Interoperability, and improvement activities performance categories, as well as the exemption for qualified registries who serve specialties that are exempt from the Promoting Interoperability performance category.

Response: We thank the commenters for their support.

Comment: A few commenters noted that the proposal should not be considered until after the final 21st Century Cures rules are published and the updated standards are implemented.

Response: We understand the interest in coordinating with the updates to standards that may be included in the 21st Century Cures Act final rule, however we do not believe that the proposals under the 21st Century Cures Act will have a significant impact on the ability of qualified registries to report measures for the Promoting Interoperability category. We note this requirement was proposed with a delayed implementation, beginning with the 2023 MIPS payment year (2021 performance period), which should accommodate timing for any updates to standards. When the 21st Century Cures Act final rule is published we will determine if additional modifications are necessary and may address in future rule making.

Comment: One commenter cited its opinion that if the proposal is finalized, the resulting burden may result in many qualified registries electing to reevaluate their decisions to seek approval to submit MIPS data.

Response: While we understand that this requirement may add burden to qualified registries, we want to note a majority of existing qualified registries already support all three performance categories. In addition, we believe it is important that qualified registries act as one-stop-shops for reporting to reduce the reporting burden on eligible clinicians and groups.

Comment: Multiple commenters also stated their opinion that if the proposal to require qualified registries to support the three performance categories is finalized, they would need CMS to provide additional guidance and descriptions of what data would be necessary to validate that an individual MIPS eligible clinician or group could appropriately attest to a specific activity.

Response: Under our current data validation processes, as described in the CY 2017 Quality Payment Program final rule (81 FR 77368 through 77369) and (81 FR 77384 through 77385), QCDRs and qualified registries are required to provide information on their sampling methodology. For example, it is encouraged that 3 percent of TIN/NPIs submitted be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of 5 patients (with a maximum sample of 50 patients). We would expect that this review of patient medical records would be done to validate that the pertinent quality actions were done for measures and activities done by the clinician and group. In addition, validation guidance clarifications can be found within the improvement activities validation document at the *MIPS Data Validation Document* link. Third party intermediaries should utilize existing validation procedures to audit data submitted. With regards to auditing whether improvement activities have been completed by a clinician or group, a third party vendor can validate that an action has been done through review of medical records or other forms of documentation that will indicate that the quality action and/or improvement activity has been completed.

Comment: One commenter requested that CMS provide a mechanism for exempting MIPS qualified registries approved for the 2019 MIPS performance period if they submit a rationale for not supporting all three performance categories.

Response: We clarify that this requirement to support all three performance categories will take into effect starting with the 2021 performance period. Qualified registries will be required to support the quality and improvement activity performance categories. A third party intermediary may not be required to submit data for the Promoting Interoperability performance category if it only represents MIPS eligible clinicians, groups, and virtual groups that are eligible for reweighting under the Promoting Interoperability performance category. For example, as discussed in the CY 2019 PFS final rule (83 FR 59819 through 59820), physical therapists generally are eligible for reweighting of the Promoting Interoperability performance category to zero percent of the final score; therefore, under this exception, a QCDR or qualified registry that represents only physical therapists that reweighted the Promoting Interoperability performance category to zero percent of the final score, would not be required to support the Promoting Interoperability performance category. In addition, QCDRs or

qualified registries that supported one of the following clinician types (and no others): Occupational therapists; qualified speech-language pathologists; qualified audiologists; clinical psychologists; and registered dieticians or nutrition professionals, as described in § 414.1380(c)(2)(i)(A)(4) would be excepted from supporting the Promoting Interoperability performance category. In contrast, a QCDR or qualified registry cannot be excepted from this requirement and must be able to submit data for the Promoting Interoperability performance category so long as it supports any clinician, group or virtual group that uses CEHRT and is not identified as eligible for reweighting of the Promoting Interoperability performance category.

After consideration of the comments, we are finalizing our proposals with technical modifications for clarity and consistency with the existing provisions of § 414.1400. As discussed in section III.K.3.g.(1), above in this final rule, we are amending § 414.1400(a)(2) to state that beginning with the 2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the MIPS performance categories identified in the regulation, and Health IT vendors must be able to submit data for at least one such category. We are also finalizing our proposal to amend § 414.1400(a)(2)(iii), as proposed, to state that for the Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) or (*5*) or § 414.1380(c)(2)(i)(C)(*1*) through (*7*) or § 414.1380(c)(2)(i)(C)(*9*)). We will require qualified registries to attest to the ability to submit data for these performance categories, as applicable, at time of self-nomination (84 FR 40819 through 40821).

(ii) Enhanced Performance Feedback Requirement

Section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through qualified registries. In addition, in establishing the requirements, the Secretary must consider, among other things, whether an entity ''provides timely performance reports to participants at the individual participant level''. Currently, CMS requires qualified registries to provide feedback on all of the MIPS performance categories at least 4 times per year (81 FR 77367 through 77386). While based on our experiences thus far during the initial years of the Quality Payment Program, we agree that providing feedback at least 4 times a year is appropriate. However, in the future CMS would like to see, and therefore, encourages qualified registries, to provide timely feedback on a more frequent basis more than 4 times a year. Receipt of more frequent feedback will help clinicians and groups make more timely changes to their practice to ensure the highest quality of care is being provided to patients. We see value in providing more timely feedback to meet the objectives [119] of the Quality Payment Program in improving the care received by Medicare beneficiaries, lowering the costs to the Medicare program through improvement of care and health, and advance the use of healthcare information between allied providers and patients. We also believe there is value in this performance feedback, and therefore, encourage qualified registries to work with their clinicians to get the data in earlier in the reporting period so the qualified registry give that meaningful timely feedback.

Surrounding the qualified registry performance feedback provided to clinicians and groups, we have heard from stakeholders that not all qualified registries provide feedback the same way. We have heard through stakeholder comments some qualified registries feedback contains information needed to improve quality, whereas other qualified registries feedback does not supply such information due to the data collection timeline. Additionally, we believe that clinicians would benefit from feedback on how they compare to other clinicians who have submitted data on a given MIPS quality measure within the qualified registry they are reporting through, so they can identify areas of measurement in which improvement is needed, and furthermore they can see how they compare to their peers based within a qualified registry, since the feedback provided by the qualified registry would be limited to those who reported on a given measure using that specific qualified registry.

As a result, we proposed to add a new paragraph at § 414.1400(c)(2) to require (i) and (ii) (84 FR 40820). We simply proposed to revise the current § 414.1400(c)(2) to reclassify at paragraph (c)(2)(i) that beginning with the 2022 MIPS payment year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period (84 FR 40820). Additionally, we proposed to add a new paragraph, § 414.1400(c)(2)(ii), beginning with the 2023 MIPS payment year, to require that qualified registries provide the following as a part of the performance feedback given at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registry (84 FR 40820). We understand that there would be instances in which the qualified registry cannot meet this requirement; and therefore, we also proposed an exception to this requirement: If the qualified registry does not receive the data from their clinician until the end of the performance period, this will preclude the qualified registry from providing feedback 4 times a year, and the qualified registry could be excepted from this requirement (84 FR 40820). We also solicited comment on other exceptions that may be necessary under this requirement.

We also understand that qualified registries can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the qualified registry does not have access to. We believe qualified registry internal comparisons can still help MIPS eligible clinicians identify areas where further improvement is needed. The ability for MIPS eligible clinicians to be able to know in real time how they are performing against their peers, within a qualified registry, provides immediate actionable feedback.

Furthermore, in the CY 2020 PFS proposed rule (84 FR 40820), we also proposed to strengthen the qualified registry self-nomination process at § 414.1400(c)(1) to add that beginning with the 2023 MIPS payment year, qualified registries are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(c)(2)(ii)). We refer readers to section III.K.3.g.(3)(1) of this final rule where we discuss a parallel requirement for QCDRs (84 FR 40814); we intend to have the same requirements for both QCDRs and qualifies registries.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal for qualified registries to provide enhanced performance feedback at least 4 times a year including comparisons to other

[119] Quality Payment Program Overview. *https://qpp.cms.gov/about/qpp-overview.*

clinicians who reported the same measure, at minimum. A few commenters agreed with the proposal that beginning in 2021, feedback from qualified registries must be provided at least 4 times a year and must include information on how participants compare to other clinicians within the qualified registry who have submitted data on a given measure. Commenters noted that this feedback and comparison is very beneficial to their participants and helps them identify potential areas for performance improvement as compared to their peers.

Response: We thank the commenters for their support.

Comment: Other commenters expressed concern that this would not provide participants with feedback on their performance from a programmatic perspective as a single registry does not represent a participant's entire peer cohort and providing registry-specific comparative performance feedback to compare their performance with that of their peers or predict their potential MIPS performance. Instead, the commenters stated their belief that it would be more appropriate to compare a MIPS eligible clinician or group's performance against the published benchmark.

Response: We thank the commenter for raising this concern. To clarify, the intent of providing eligible clinicians and groups with this performance feedback is to give them feedback on how they compare to other clinicians (their peers) who have submitted data on a given MIPS quality measure within the qualified registry they are reporting through. Additionally, the intent of this feedback is so clinicians can identify areas of quality measurement in which improvement is needed, and furthermore, they can see how they compare to their peers based within a qualified registry. While we understand that it is not feasible for a single registry to represent the cohort of all clinicians who have reported on a given measure, it at least gives the clinicians within the single registry an idea of how well they performed with other fellow clinicians within the registry. We believe that it is important to provide meaningful data back to clinicians to understand and identify areas for improvement. We are only able to compare a MIPS eligible clinician or group's performance against a published benchmark when the qualified registry measure has reached the appropriate benchmarking and reporting thresholds, after the submission period for a given performance period closes. However, we believe it is important that clinicians and groups receive performance feedback in a timely fashion, by their qualified registry, in order to make real-time process improvements to their practice to improve the quality of care.

After consideration of the comments, we are finalizing our proposals as proposed. Specifically, we are amending § 414.1400(c)(2) to add (i) and (ii). We are amending the current § 414.1400(c)(2) to reclassify at paragraph (c)(2)(i) that beginning with the 2022 MIPS payment year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period. Additionally, we are also finalizing a new paragraph at § 414.1400(c)(2)(ii) to require that, beginning with the 2023 MIPS payment year, qualified registries provide the following as a part of the performance feedback given at least 4 times a year, provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registry. We are also finalizing an exception to this requirement: If the qualified registry does not receive the data from their clinician until the end of the performance period, this will preclude the qualified registry from providing feedback 4 times a year, and the qualified registry could be excepted from this requirement. We are also finalizing, as proposed, at § 414.1400(c)(1) to add that beginning with the 2023 MIPS payment year, qualified registries are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(c)(2)(ii)).

In the CY 2020 PFS proposed rule (84 FR 40814), we sought comment for future notice-and-comment rulemaking on whether we should require MIPS eligible clinicians, groups, and virtual groups who utilize a qualified registry to submit data throughout the performance period, and prior to the close of the performance period (that is, December 31st). The current performance period begins January 1 and ends on December 31st, and the corresponding data submission deadline is typically March 31st as described at § 414.1325(e)(1). We also sought comment for future notice-and-comment rulemaking, on whether clinicians and groups can start submitting their data starting April 1 to ensure that the qualified registry is providing feedback and the clinician or group during the performance period. This would allow qualified registries some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.

While we are not summarizing and responding to comments we received on this topic in this final rule, we thank the commenters for their responses and will take them into consideration as we develop future policies for qualified registries.

(5) Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(f), the CY 2017 Quality Payment Program final rule (81 FR 77548) and the CY 2019 PFS final rule (83 FR 59908 through 59910) for previously finalized policies for remedial action and termination of third party intermediaries.

As explained in the CY 2020 PFS proposed rule (84 FR 40820), based on experience with third party intermediaries thus far, we have concerns that certain third party intermediaries may not fully appreciate their existing compliance obligations or the implications of non-compliance. Among other provisions, § 414.1400(a)(5) specifically obligates each third party intermediary to certify that all data it submits to CMS on behalf of a MIPS eligible clinician, group or virtual group is true, accurate and complete to the best of its knowledge. Section 414.1400(f)(1) states that, after providing written notice, CMS may take remedial action or terminate a third party intermediary if CMS determines that the third party intermediary has ceased to meet one or more of the applicable criteria for approval or has submitted data that is inaccurate, unusable or otherwise compromised. Moreover, § 414.1400(f)(3) identifies specific circumstances under which CMS may determine that data submitted by a third party intermediary meets the standard for inaccurate, unusable or otherwise compromised data.

Third parties intermediaries have an affirmative obligation to certify that the data they submit on behalf of a MIPS eligible clinician, group or virtual group are true, accurate and complete to the best of its knowledge. MIPS data that are inaccurate, incomplete, unusable or otherwise compromised can result in improper payment. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period, commonly referred to as ''cherry-picking,'' results in data submissions that are not true, accurate or complete. A third party intermediary cannot certify that data submitted to CMS by the third party intermediary are true, accurate and complete to the best of its knowledge if the third party intermediary knows the data submitted

are not representative of the clinician's or group's performance. Accordingly, a third party intermediary that submits a certification under § 414.1400(a)(5) in connection with the submission of data it knows are cherry-picked has submitted a false certification in violation of existing regulatory requirements. If CMS believes cherry-picking of data may be occurring, we may subject the third party intermediary and its clients to auditing in accordance with § 414.1400(g).

In the CY 2020 PFS proposed rule (84 FR 40821), we explained that despite these existing obligations, we have received inquiries from third party intermediaries regarding perceived opportunities to selectively submit data that are unrepresentative of the MIPS performance of the clinician or group for which the third party intermediary is submitting data. These inquires suggest that certain third party intermediaries may not fully appreciate their current regulatory obligations or their implications.

The current regulations at § 414.1400(f) clearly establish that CMS enforcement authority includes the authority to pursue remedial actions or termination based on its determination that a third party intermediary was non-compliant with any applicable criteria for approval in § 414.1400(a) through (e) or if the third party intermediary submitted data that are inaccurate, unusable or otherwise compromised. Compliance with § 414.1400(a)(5) is a criteria for approval. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period results in data that are inaccurate, unusable and otherwise compromised. Accordingly, if CMS determined that third party intermediary knowingly submitted data that are not representative of the clinician's or group's performance and certified that the submitted data were true, accurate and complete, CMS would have multiple grounds to impose remedial action or termination under existing regulations.

As described in the CY 2020 PFS proposed rule (84 FR 40821), we proposed two changes to more expressly emphasize CMS enforcement authority. First, we proposed to clarify that remedial action and termination provisions at § 414.1400(f)(1) are triggered if we determine that a third party intermediary submits a false certification under paragraph (a)(5). Second, we proposed to clarify that CMS authority to bring remedial actions or terminate a third party intermediary for submitting data that is inaccurate, unusable or otherwise compromise extends beyond the specific examples set forth in § 414.1400(f)(3). We explained that with these revisions and a grammatical correction proposed at § 414.1400(f)(1), we would affirm existing CMS authority to purse remedial actions or termination if we determine that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, submits a false certification under paragraph (a)(5), or has submitted data that are inaccurate, incomplete, unusable, or otherwise compromised (84 FR 40821). We noted that we anticipate that these revisions will emphasize to third party intermediaries the sanctions they may face from CMS if they submit improper data to CMS. In addition, we noted that third party intermediaries may face liability under the federal False Claims Act if they submit or cause to submission of false MIPS data.

We proposed revisions to § 414.1400(f)(3) to clarify the intent of this provision (84 FR 40821). We also refer readers to CY 2019 PFS final rule (83 FR 59908 through 59910) for the discussion of the evolution of policies regarding remedial actions and termination of a third party intermediary. The agency's enforcement authority as codified in § 414.1400(f) broadly extends to include instances of willful misconduct by the third party intermediary and well as other instances in which a third party intermediary inadvertently submits data with deficiencies and errors that render the data ''inaccurate, unusable or otherwise compromised.'' To facilitate a more fulsome understanding on when inadvertent conduct could trigger an enforcement action against a third party intermediary, the current regulatory text in § 414.1400(f)(3) provides that the threshold for ''inaccurate, unusable or otherwise compromised'' may be met if the submitted data includes TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies that affect more 3 percent of the total number of MIPS eligible clinicians or groups for which data was submitted by the third party intermediary. Through the CY 2020 PFS proposed rule (84 FR 40821), we proposed to add the phrase ''including but not limited to'' to the text of § 414.1400(f)(3) to emphasize that this provision is illustrative of circumstances that may result in enforcement action and should not be misinterpreted to limit the agency's ability to impose remedial actions or terminate a third party intermediary that knowingly submits inaccurate data.

Lastly, we proposed grammatical corrections related to the use of the plural term ''data'' (84 FR 40821).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for CMS conducting audits if we believe data have been ''cherry-picked'' or are otherwise not accurate.

Response: We thank commenters for their support.

Comment: Another commenter further encouraged CMS to publish aggregate information from their 2018 auditing of MIPS eligible clinicians and groups with regard to suspected instances of cherry-picked data in regard to third party intermediaries.

Response: We thank the commenter for their suggestion, and would encourage them to clarify what type of aggregated data they are looking for as these types of audit results are not typically published.

Comment: A few commenters stated that although CMS has provided some indication of what may constitute an inaccuracy, greater clarity and transparency is critical so that registries can implement appropriate checks and identify additional data inaccuracies or errors beyond those that are detected through each registry's CMS approved data validation plan. The commenters further urged CMS to: Clearly define a registry's responsibility to address data inaccuracies that can be attributed to data that the registry has access to, controls and manages; consider developing a report that describes and differentiates errors, as well as other ''issues'' that should be brought to the registry's attention; clearly define what is considered when calculating an error rate; and provide additional detail regarding CMS' description of criteria that may disqualify a third-party intermediary. One commenter specifically stated its belief that when individuals or practices withhold Medicare billing data, this unavailable data should not be counted against the registry as an inaccuracy since the registry has no readily available solution to address this issue without access to current CMS' claims data. One commenter encouraged CMS to release additional instructions for individual clinicians and groups to understand their responsibilities in submitting accurate and complete data and not hold third-parties accountable for data issues outside their control.

Response: We thank the commenters for their suggestions. As described in the CY 2017 Quality Payment Program

final rule (81 FR 77366 through 77374), and through our resources in the Quality Payment Program Resource Library, such as our 2020 Self-Nomination Tool Kit for QCDR and qualified registries: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/580/2020%20Self-Nomination%20Toolkit%20for%20QCDRs%20%26%20Qualified%20Registries.zip* we provide further descriptions of the expectations of data validation plans and examples of what would constitute data inaccuracies, including the guidance that the QCDR should make CMS aware of any errors that may impact a clinician's ability to report or how the clinician may score on a measure or overall. We refer commenters to the MIPS Data Validation Execution Report (DVER) template and the self-nomination factsheet for further details on expectations of data validation and discussion of remedial action and termination due to these error rates, both documents can be found on the Quality Payment Program Resource Library *https://qpp.cms.gov/about/resource-library.* In addition, on a monthly basis through our mandatory support calls (81 FR 77368), we have typically reminded our approved QCDRs and qualified registries of our expectations for the data validation execution report and the methodology for calculating error rates and we anticipate using these calls and other guidance for additional education of third party intermediaries in the future. We will look to provide additional education to clinicians and groups in understanding their responsibility to help ensure the data submitted on their behalf by third party intermediaries are true, accurate, and complete data. However, we believe third parties intermediaries are also accountable for the accuracy of what they submit to CMS. If a third party intermediary finds inaccuracies or data integrity issues, it should ensure that it does not knowingly submit data that are misrepresentative, and are not true, accurate, or complete. We will take the commenters suggestions into future consideration.

Comment: A few commenters requested clarification on whether specific scenarios involved data inaccuracies that would trigger remedial action. One commenter sought clarification on whether a data submission is inaccurate if the submission misstates whether a clinician is a non-MIPS eligible clinician, a Qualified APM Participant or other APM participant; and if that misstatement would trigger a remedial action under § 414.1400(f). Another commenter sought clarification as to whether a qualified registry would be subject to remedial action if the data submitted did not meet appropriate data completeness thresholds.

Response: We believe it is the responsibility of the third party intermediary to validate data prior to submission to CMS and to ensure that the data is true, accurate, and complete to the best of its knowledge. This certification is applicable to information regarding a clinician's eligibility status. We expect that data submitted by third party intermediaries are true, accurate and complete to the best of the submitter's knowledge. If a third party intermediary knows data are not true, accurate or complete, the third party intermediary should not submit those data. Whether CMS will bring remedial action or terminate a third party intermediary under § 414.1400(f) for submitting a false certification or for submitting data that are inaccurate, unusable or otherwise compromised depends on the particular facts and circumstances. If a third party intermediary submits data that misstate whether a clinician is non-eligible, a Qualified APM Participant, or other APM participant then the third party intermediary has submitted data that are inaccurate. We believe that third party intermediaries should be able to track the eligibility status of the clinicians and groups they support MIPS reporting for, particularly as it pertains to MIPS eligible, voluntary participation, and opt-ins. That is to also to account for those clinicians and groups who have chosen to opt-in participating in the program. If we determine a third party intermediary is misrepresenting the status of its clinicians, we would anticipate seeking a corrective action plan from the third party intermediary to address these deficiencies. If its submission meets applicable program requirements, such as a submission of data on a single patient to meet a minimum threshold, a third party intermediary may be able to accurately certify that the data it is submitting are true, accurate and complete even if the data does not meet the data completeness threshold for an individual eligible clinician. Data submissions that do not meet appropriate data completeness thresholds (as described in section III.K.3.c of this final rule) will not receive an error message from the system, and will be scored according to the scoring regulations at § 414.1380. If the data submitted does not satisfy the data completeness thresholds, the submission is unlikely to receive full credit, and will be scored accordingly; however, this alone would not render the third party intermediary's submission incomplete for purposes § 414.1400. Through our resources in the Quality Payment Program Resource Library, known as our 2020 Self-Nomination Tool Kit (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/580/2020%20Self-Nomination%20Toolkit%20for%20QCDRs%20%26%20Qualified%20Registries.zip*), we provide further descriptions of the expectations of data validation plans and examples of what would constitute data inaccuracies. Failure to comply with program regulations could result in remedial action. From the data error perspective, we remind third party intermediaries that they are expected to certify that their data submissions are true, accurate, and complete to the best of their knowledge.

Comment: One commenter expressed their belief that the provision in § 414.1400(f)(3)(ii) which gives weight to data errors that affect 3 percent of the MIPS eligible clinicians and groups whose data was submitted by the third party intermediary may unfairly penalize third party intermediaries with a small number of participants. The commenter provided the example that a quality registry reporting for only 25 clinicians triggering the 3 percent threshold if its submission included a data error on a single patient of a single clinician. The commenter recommended revising the provision such that the threshold was measured based on the percentage of patients reported by third party intermediary rather than the percentage of clinicians.

Response: We believe it is important to hold third party intermediaries responsible for data errors regardless of the volume of clinicians and groups they support. Third party intermediaries with smaller volumes of reporting clinicians and groups should be able to ensure the accuracy of the data they submit and have fewer errors when compared to larger third party intermediaries. To facilitate a more fulsome understanding on when inadvertent conduct could trigger an enforcement action against a third party intermediary, the current regulatory text in § 414.1400(f)(3) provides that the threshold for ''inaccurate, unusable or otherwise compromised'' may be met if the submitted data includes TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies that affect more 3 percent of the total number of MIPS eligible

clinicians or groups for which data was submitted by the third party intermediary. Through the CY 2020 PFS proposed rule (84 FR 40821), we proposed to add the phrase ''including but not limited to'' to the text of § 414.1400(f)(3) to emphasize that this provision is illustrative of circumstances that may result in enforcement action and should not be misinterpreted to limit the agency's ability to impose remedial actions or terminate a third party intermediary that knowingly submits inaccurate data. We disagree with the commenter's suggestion to revise the policy to state that the threshold should be measures based on the percentage of patients reported by the third party intermediaries rather than the percentage of clinicians because this auditing at the patient level does not allow us to determine the overall impact of the data error to the cohort of clinicians who utilized the third party to report. Utilizing the percentage of patients as the data error threshold may lead to inaccurate representations of the overall impact of a data error found through third party reporting.

Comment: Some commenters urged CMS to be mindful that from their perspective third party intermediaries, especially specialty society clinical data registries, do not have the capacity to tell whether a group has specifically submitted false or incomplete data. These commenters believed it is the responsibility of the MIPS eligible clinician or group to demonstrate to CMS that their data are accurate and complete using documentation as described by CMS in this rule. Moreover, if ''cherry-picking'' is found by CMS, these commenters believed the audit should be sent to the MIPS eligible clinician or group, and not the third party intermediary.

Response: We believe it is the responsibility of the third party intermediary to validate data prior to submission to CMS and to ensure that the data it submits are true, accurate, and complete to the best of its knowledge. It should be a joint responsibility of the eligible clinician and the third party intermediary to ensure that data submitted to CMS is true and reflective of their scope of practice, while avoiding selection bias.

After consideration of the comments, we are finalizing our proposals as proposed. Specifically, we are finalizing that remedial action and termination provisions at § 414.1400(f)(1) are triggered if we determine that a third party intermediary submits a false certification under paragraph (a)(5). Additionally, we are finalizing that CMS authority to bring remedial actions or terminate a third party intermediary for submitting data that are inaccurate, unusable or otherwise compromised extends beyond the specific examples set forth in § 414.1400(f)(3). We added the phrase ''including but not limited to'' to the text of § 414.1400(f)(3) to emphasize that this provision is illustrative of circumstances that may result in enforcement action and should not be misinterpreted to limit the agency's ability to impose remedial actions or terminate a third party intermediary that knowingly submits inaccurate data. In addition, we note that third party intermediaries may face liability under the federal False Claims Act if they submit or cause to submission of false MIPS data.

Lastly, we are finalizing the corrections related to the use of the plural term of ''data.''

h. Public Reporting on Physician Compare

(1) Background

For previous discussions on the background of Physician Compare, we refer readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), and the Physician Compare Initiative website at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/.*

We proposed to publicly report on Physician Compare: (1) Aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY 2019), as technically feasible; and (2) an indicator on the profile page or in the downloadable database that displays if a MIPS eligible clinicians is scored using facility-based measurement, as specified under § 414.1380(e)(6)(vi), as technically feasible (see 84 FR 40821 through 40824). A summary of the comments received and our finalized policies are discussed in more detail in this final rule.

(2) Regulation Text Changes

Section 1848(q)(9)(A) and (D) of the Act requires that we publicly report on Physician Compare in an easily understandable format:

- The final score for each MIPS eligible clinician;
- Performance of each MIPS eligible clinician for each performance category;
- Periodic aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category; and
- The names of eligible clinicians in advanced APMs and, to the extent feasible, the names of such advanced APMs and the performance of such APMs.

Section 1848(q)(9)(B) of the Act requires that the information made available under section 1848(q)(9) of the Act must indicate, where appropriate, that publicized information may not be representative of the eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

To more completely and accurately reference the data available for public reporting on Physician Compare, we proposed to amend § 414.1395 by adding paragraph (a)(1) stating that CMS posts on Physician Compare, in an easily understandable format: (i) Information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and (ii) the names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs. As discussed in section III.K.3.h.(3) of this final rule, we also proposed to amend § 414.1395 by adding paragraph (a)(2) stating that CMS periodically posts on Physician Compare aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category. Finally, we proposed to amend § 414.1395 by adding paragraph (a)(3) stating that the information made available under § 414.1395 will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

We did not receive public comments on the proposed regulation text changes. As such, we are finalizing our policy as proposed to amend § 414.1395 by adding paragraph (a)(1) stating that CMS posts on Physician Compare, in an easily understandable format: (1) Information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and

performance category scores for each MIPS eligible clinician; and (2) the names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs. In addition, we are finalizing our policy as proposed to amend § 414.1395 by adding paragraph (a)(3) stating that the information made available under § 414.1395 will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

(3) Final Score, Performance Categories, and Aggregate Information

Section 1848(q)(9)(D) of the Act requires the Secretary to periodically post on Physician Compare aggregate information on the MIPS, including the range of composite scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53823), where we previously finalized policies to publicly report on Physician Compare, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category, and to periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years.

Although we previously finalized a policy to periodically post aggregate information on the MIPS, as technically feasible, for all future years, we have not proposed or finalized in rulemaking a specific timeframe for doing so. As part of our phased approach to public reporting, we wanted to first gain experience with the MIPS data prior to publicly reporting it in aggregate, since we had not publicly reported on Physician Compare aggregate data under legacy programs. For example, we publicly reported the Physician Quality Reporting System (PQRS) performance information only at an individual clinician and group practice level. Now that we have experience with the MIPS data, including the Year 1 performance information which was not available for analysis at the time of prior rulemaking, we can now propose a specific timeframe for publicly reporting aggregate MIPS data on Physician Compare.

Therefore, in accordance with section 1848(q)(9)(D) of the Act, we proposed to publicly report on Physician Compare aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY 2019), as technically feasible, and to codify this policy at § 414.1395(a) (84 FR 40822). We clarify that the aggregate data publicly reported would be inclusive of all MIPS eligible clinicians. We also note that some aggregate MIPS data is already publicly available in other places, such as via the Quality Payment Program Experience Report. We note that the 2017 Quality Payment Program Experience Report is available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/491/2017%20QPP%20Experience%20Report.pdf.* As noted in the CY 2018 Quality Payment Program final rule (82 FR 53823), we will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel, to determine how and where these data are best reported on Physician Compare (for example in the Physician Compare Downloadable Database or on the Physician Compare Initiative page). In addition to minimum and maximum MIPS performance category and final scores, we also solicited comment on any other aggregate information that stakeholders will find useful for future public reporting on Physician Compare.

We received public comments on other aggregate information that stakeholders will find useful for future public reporting on Physician Compare. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported publicly reporting aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (2018 data available starting in late 2019). A few commenters supported the goals of public reporting information on Physician Compare yet remained concerned that Medicare patients and their caregivers may not be able to accurately understand and interpret aggregated information, such as the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians. Two commenters supported publicly reporting information on Physician Compare, but expressed concern about the accuracy of the data while another commenter that supported public reporting also noted that publishing aggregate information may not be meaningful for certain clinician types. One commenter recommended delaying publicly reporting aggregate information until concerns around accuracy of the data can be resolved.

Response: We appreciate commenters support and the concerns raised. We note that section 1848(q)(9)(D) of the Act requires the Secretary to periodically post on Physician Compare aggregate information on the MIPS, including the range of composite scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category. In addition, we will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel, to determine how and where these data are best reported on Physician Compare to ensure these data are understood and interpreted accurately. We believe we should employ the same phased approach to ensure the data made public accurately represents clinical performance and is understood by website users. We will actively work to ensure that the language on the website and the additional education and outreach conducted for patients and caregivers continues to make this information clear. In addition, we will work to ensure all data publicly reported on Physician Compare is accurate. As such, all data available for public reporting are available for review and correction during the targeted review process, as specified at § 414.1385. Data under review will not be publicly reported until the review is complete. We clarify that aggregate data will reflect MIPS eligible clinicians and groups collectively and will not be specialty-specific.

After consideration of the comments, we are finalizing our proposal to publicly report on Physician Compare aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY 2019), as technically feasible. We are also finalizing our proposal to amend § 414.1395 by adding paragraph (a)(2) stating that we periodically post on Physician Compare aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible

clinicians with respect to each performance category.

(4) Quality

For previous discussions on publicly reporting quality performance category information on the Physician Compare website, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53824) and the CY 2019 Quality Payment Program final rule (83 FR 59912).

Although we did not make any proposals regarding publicly reporting quality performance category information, we solicited additional comments on adding patient narratives to the Physician Compare website in future rulemaking, to the extent consistent with our authority to collect such information under section 1848(q) of the Act and our authority to include an assessment of patient experience and patient, caregiver, and family engagement under section 10331(a)(2)(E) of the Affordable Care Act.

Physician Compare website user testing has repeatedly shown that Medicare patients and caregivers greatly desire narrative reviews, quotes and testimonials by their peers, and a single overall ''value indicator,'' reflective for each MIPS eligible clinician and group, and will expect to find such information on the Physician Compare website already, based on their experiences with other consumer-oriented websites. We currently do not display any narrative patient satisfaction information on Physician Compare or any single overall value indicator for MIPS eligible clinicians and groups (except MIPS performance category and final scores); currently all performance information on Physician Compare is publicly reported at the individual measure level. Therefore, we solicited comment on the value of and considerations for publicly reporting such information to assist patients and caregivers with making healthcare decisions, building upon the feedback received in response to the CY 2018 Quality Payment Program proposed rule (82 FR 30166 through 30167), in which we specifically sought comment on publicly reporting responses to five open-ended questions that are part of the Agency for Healthcare Research and Quality (AHRQ)'s CAHPS Patient Narrative Elicitation Protocol (*https://www.ahrq.gov/cahps/surveys-guidance/item-sets/elicitation/index.html*). While we are not summarizing and responding to comments we received in this final rule, we appreciate the responses from the commenters and may take them into account as we develop future policies for public reporting on Physician Compare.

We refer readers to section III.K.3.c.(1)(c)(i) of this final rule for an additional solicitation for comments to add narrative reviews into the CAHPS for MIPS group survey in future rulemaking.

To be publicly reported on Physician Compare, patient narrative data will have to meet our public reporting standards, described at § 414.1395(b), and reviewed in consultation with the Physician Compare Technical Expert Panel, to determine how and where these data would be best reported on Physician Compare. We solicited comment on the value of collecting and publicly reporting information from narrative questions and other patient-reported outcome measures (PROMs), as well as publishing a single ''value indicator'' reflective of cost, quality and patient experience and satisfaction with care for each MIPS eligible clinician and group, on the Physician Compare website and will consider feedback from the patient, caregiver, and clinician communities before proposing any policies in future rulemaking. We also noted that if we propose to publicly report patient narratives in future rulemaking, we will address all related patient privacy safeguards consistent with section 10331(c) of the Affordable Care Act, which requires that information on physician performance and patient experience is not disclosed in a manner that violates the Freedom of Information Act (5 U.S.C. 552) or the Privacy Act of 1974 (5 U.S.C. 552a) with regard to the privacy individually identifiable health information, and other applicable law. While we are not summarizing and responding to comments we received in this final rule, we appreciate the responses from the commenters and may take them into account as we develop future policies for public reporting on Physician Compare.

(5) Promoting Interoperability

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53827) and the CY 2019 Quality Payment Program final rule (83 FR 59913) for previously finalized policies related to the Promoting Interoperability performance category and Physician Compare.

Although we did not make any proposals regarding publicly reporting Promoting Interoperability category information, we refer readers to the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally Facilitated Exchanges and Health Care Providers'' proposed rule (referred to as the Interoperability and Patient Access proposed rule) published in the March 4, 2019 **Federal Register** (84 FR 7646 through 7647), where we proposed to include an indicator on Physician Compare for the eligible clinicians and groups that submit a ''no'' response to any of the three prevention of information blocking attestation statements in § 414.1375(b)(3)(ii)(A) through (C). To report successfully on the Promoting Interoperability performance category, in addition to satisfying other requirements, a MIPS eligible clinician must submit an attestation response of ''yes'' for each of these statements. These statements contain specific representations about a clinician's implementation and use of CEHRT and are intended to verify that a MIPS eligible clinician has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology. In the event that these statements are left blank, that is, a ''yes'' or a ''no'' response is not submitted, the attestations would be considered incomplete, and we would not include an indicator on Physician Compare. We also proposed to post this indicator on Physician Compare, either on the profile pages or the downloadable database, as feasible and appropriate, starting with the 2019 performance period data available for public reporting starting in late 2020. We refer readers to the CY 2017 Quality Payment Program final rule for additional information on these attestation statements (81 FR 77028 through 77035).

(6) Facility-Based Clinician Indicator

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53823), we finalized a policy to publicly report the MIPS performance category and final scores earned by each MIPS eligible clinician on Physician Compare, either on profile pages or in the downloadable database. We also finalized that we will make all measures under the MIPS quality performance category available for public reporting on Physician Compare, either on profile pages or in the downloadable database, as technically feasible (82 FR 53824). We will use statistical testing and user testing to determine how and where measures are reported on Physician Compare. We established at

§ 414.1380(e) a facility-based measurement scoring option under the MIPS quality and cost performance categories for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year. Section 414.1380(e)(1)(ii) provides that the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period.

With this in mind, we have considered how to best display facility-based MIPS eligible clinician quality and cost information on Physician Compare, appreciating our obligation to publicly report certain MIPS data for MIPS eligible clinicians and groups. As those clinicians and groups scored under the facility-based option are MIPS eligible, we will publicly report their performance category and MIPS final scores on Physician Compare and considered two options for publicly reporting their facility-based measure-level performance information on Physician Compare: (a) Displaying hospital-based measure-level performance information on Physician Compare profile pages, including scores for specific measures and the hospital overall rating; or (b) including an indicator showing that the clinician or group was scored using the facility-based scoring option with a link from the clinician's Physician Compare profile page to the relevant hospital's measure-level performance information on Hospital Compare. We believe that a link from the clinician's Physician Compare profile page to the relevant hospital's performance information on Hospital Compare is preferable for several reasons including: Concerns about duplication with Hospital Compare, interpretability by Physician Compare website users expecting to find clinician-level, rather than hospital-level, information and operational feasibility. Additionally, we believe this approach is consistent with our consumer testing findings that Medicare patients and caregivers find value in information on the relationships clinicians and groups may have with facilities where they perform services. We note that the facility-based scoring indicator would be separate from the hospital affiliation information for admitting privileges currently posted on Physician Compare profile pages.

For these reasons, we proposed to make available for public reporting an indicator on the Physician Compare profile page or downloadable database that displays if a MIPS eligible clinician is scored using facility-based measurement, as specified under § 414.1380(e)(6)(vi), as technically feasible (84 FR 40824). We also proposed to provide a link to facility-based measure-level information, as specified under § 414.1380(e)(1)(i), for such MIPS eligible clinicians on Hospital Compare, as technically feasible. In addition, we proposed to post this indicator on Physician Compare with the linkage to Hospital Compare beginning with CY 2019 performance period data available for public reporting starting in late CY 2020 and for all future years, as technically feasible. We requested comment on this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported making available for public reporting an indicator on the Physician Compare profile page or downloadable database that displays if a MIPS eligible clinician is scored using facility-based measurement and provide a link to facility-based measure-level information for such MIPS eligible clinicians on Hospital Compare, as technically feasible. One commenter supported the goals of public reporting information on Physician Compare yet remained concerned that Medicare patients and their caregivers may not be able to accurately understand and interpret the facility-based indicator. A few commenters supported publicly reporting the facility-based indicator and recommended providing context and/or CMS providing explanatory text mentioning that facility-level measures assess care provided at a facility level, rather than a clinician or group level.

Response: We note that findings from our consumer testing indicate that Medicare patients and caregivers find value in information on the relationships clinicians and groups may have with facilities where they perform services. In addition, we note that with the exception of data that must be mandatorily reported on Physician Compare, data included on Physician Compare must meet our public reporting standards, as described at § 414.1395(b). This means data included on Physician Compare public facing profile pages must resonate with website users as determined by CMS. We will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel, to determine how and where these data are best reported on Physician Compare, including either on profile pages or the downloadable database and to provide the appropriate context and explanatory text for Medicare patients and caregivers.

After consideration of the comments, we are finalizing our proposal to make available for public reporting an indicator on the Physician Compare profile page or downloadable database that displays if a MIPS eligible clinician is scored using facility-based measurement, as specified under § 414.1380(e)(6)(vi), as technically feasible. We are also finalizing our proposal to provide a link to facility-based measure-level information, as specified under § 414.1380(e)(1)(i), for such MIPS eligible clinicians on Hospital Compare, as technically feasible. In addition, we are finalizing our proposal to post this indicator on Physician Compare with the linkage to Hospital Compare beginning with CY 2019 performance period data available for public reporting starting in late CY 2020 and for all future years, as technically feasible.

4. Overview of the APM Incentive

a. Overview

Section 1833(z) of the Act requires that an incentive payment be made in years 2019 through 2024 (or, in years after 2025, a different PFS update) to Qualifying APM Participants (QPs) for achieving threshold levels of participation in Advanced APMs. In the CY 2017 Quality Payment Program final rule (81 FR 77399 through 77491), we finalized the following policies:

- Beginning in payment year 2019, if an eligible clinician participated sufficiently in an Advanced APM during the QP Performance Period, that eligible clinician may become a QP for the year. Eligible clinicians who are QPs are excluded from the MIPS reporting requirements for the performance year and payment adjustment for the payment year.
- For payment years from 2019 through 2024, QPs receive a lump sum incentive payment equal to 5 percent of their prior year's estimated aggregate payments for Part B covered professional services. Beginning in payment year 2026, QPs receive a differentially higher update under the PFS for the year than non-QPs.
- For payment years 2019 and 2020, eligible clinicians may become QPs only through participation in Medicare Advanced APMs.
- For payment years 2021 and later, eligible clinicians may become QPs through a combination of participation in Medicare Advanced APMs and Other Payer Advanced APMs (which we refer

to as the All-Payer Combination Option).

In the CY 2018 Quality Payment Program final rule (82 FR 53832 through 53895), we finalized clarifications, modifications, and additional details pertaining to Advanced APMs, QP and Partial QP determinations, Other Payer Advanced APMs, Determination of Other Payer Advanced APMs, Calculation of All-Payer Combination Option Threshold Scores and QP Determinations, and Physician-Focused Payment Models (PFPMs).

In the CY 2019 PFS final rule (83 FR 59915 through 59940), we finalized clarifications, modifications, and additional details pertaining to use of Certified Electronic Health Record Technology (CEHRT), MIPS-comparable quality measures, bearing financial risk for monetary losses, the QP Performance Period, Partial QP election to report to MIPS, Other Payer Advanced APM criteria, determination of Other Payer Advanced APMs, calculation of All-Payer Combination Option Threshold Scores and QP determinations under the All-Payer Combination Option.

In this final rule, we discuss policies pertaining to Advanced APMs and the All-Payer Combination Option.

b. Terms and Definitions

As we continue to develop the Quality Payment Program, we have identified the need to propose new definitions to go along with the previously defined terms. A list of the previously defined terms is available in the CY 2017 Quality Payment Program final rule (81 FR 77537 through 77540), the CY 2018 Quality Payment Program final rule (82 FR 53951 through 53952), and in the CY 2019 PFS final rule (83 FR 60075 through 60076), and reflected in our regulation at § 414.1305.

In the CY 2017 Quality Payment Program final rule, we defined the term ''Medical Home Model'' and ''Medicaid Medical Home Model.'' Since defining these terms in the CY 2017 Quality Payment Program final rule, we solicited comment on whether or not to establish a similar definition to describe payment arrangements similar to Medical Home Models and Medicaid Medical Home Models that are operated by other payers (82 FR 30180).

As discussed in the CY 2020 PFS proposed rule (84 FR 40731), we proposed to add the defined term ''Aligned Other Payer Medical Home Model'' to § 414.1305, to mean a payment arrangement (not including a Medicaid payment arrangement) operated by an other payer that formally partners with CMS in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation, such as a memorandum of understanding (MOU), and is determined by CMS to have the following characteristics:

- The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;
- Empanelment of each patient to a primary clinician; and
- At least four of the following: Planned coordination of chronic and preventive care; Patient access and continuity of care; Risk-stratified care management; Coordination of care across the medical neighborhood; Patient and caregiver engagement; Shared decision-making; and/or Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

We are finalizing this proposal. For additional discussion related to this definition of Aligned Other Payer Medical Home Model, please see section III.K.4.e of this final rule.

c. Advanced APMs

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

- Requires its participants to use certified EHR technology (CEHRT) (81 FR 77409 through 77414);
- Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (81 FR 77414 through 77418); and
- Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or is a Medical Home Model expanded under section 1115A(c) of the Act (81 FR 77418 through 77431). We refer to this criterion as the financial risk criterion.

In the CY 2018 Quality Payment Program final rule (82 FR 53832 through 53895), we finalized clarifications, modifications, and additional details pertaining to the Advanced APM criteria, Qualifying APM Participant (QP) and Partial QP determinations, the Other Payer Advanced APM criteria, Determination of Other Payer Advanced APMs, Calculation of All-Payer Combination Option Threshold Scores and QP Determinations, and we discussed Physician-Focused Payment Models (PFPMs).

In the CY 2019 PFS final rule (83 FR 59915 through 59938), we finalized the following:

Use of CEHRT:

- We revised § 414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity, or, for APMs in which hospitals are the APM Entities, each hospital, use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

MIPS-Comparable Quality Measures:

- We revised § 414.1415(b)(2) to clarify, effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases payment must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.
- We revised the requirement at § 414.1415(b)(3) that the quality measures upon which an Advanced APM bases payment must include at least one outcome measure (unless there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period) to provide, effective January 1, 2020, that at least one such outcome measure must either be finalized on the MIPS final list of measures as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

Bearing Financial Risk for Monetary Losses:

- We revised § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

In this section of the final rule, we address policies regarding several aspects of the Advanced APM criterion on bearing financial risk for monetary losses—specifically our proposal to amend the definition of expected

expenditures, and our request for comment on whether certain items and services should be excluded from the capitation rate for our definition of full capitation arrangements.

(2) Bearing Financial Risk for Monetary Losses

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77418), we divided the discussion of this criterion into two main topics: (1) What it means for an APM Entity to bear financial risk for monetary losses under an APM (which we refer to as either the generally applicable financial risk standard or Medical Home Model financial risk standard); and (2) what levels of risk we would consider to be in excess of a nominal amount (which we refer to as either the generally applicable nominal amount standard or the Medical Home Model nominal amount standard).

(b) Expected Expenditures

In the CY 2017 Quality Payment Program final rule (81 FR 77550), we established a definition of expected expenditures at § 414.1415(c)(5) to mean the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, ''expected expenditures'' means the episode target price. We established this definition of expected expenditures for the purposes of applying the Advanced APM financial risk criterion to determine whether an APM meets the generally applicable nominal amount standard.

In the CY 2017 Quality Payment Program proposed rule (81 FR 28305 through 28309), we proposed to measure three dimensions of risk under our generally applicable nominal amount standards: (1) Marginal risk, which refers to the percentage of the amount by which actual expenditures exceed expected expenditures for which an APM Entity would be liable under the APM; (2) minimum loss rate (MLR), which is a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk; and (3) total potential risk, which refers to the maximum potential payment for which an APM Entity could be liable under the APM.

However, based on commenters' concerns regarding technical complexity, we did not finalize the marginal risk and MLR components of the generally applicable nominal amount standard under the Advanced APM criteria (81 FR 77427), but did finalize those additional elements of risk under the Other Payer Advanced APM criteria. We stated in the CY 2017 Quality Payment Program final rule (81 FR 77426) that it is not necessary to include the marginal risk and MLR components in the generally applicable nominal amount standard for Advanced APMs because we are committed to creating Advanced APMs with strong financial risk designs that incorporate risk adjustment, benchmark methodologies, sufficient stop-loss amounts, and sufficient marginal risk; and that all APMs involving financial risk that we operate now or in the future would meet or exceed the proposed marginal risk and MLR requirements. In the CY 2017 Quality Payment Program proposed rule (81 FR 28306), we explained that, to determine whether an APM satisfies the marginal risk component of the generally applicable nominal amount standard, we would examine the payment required under the APM as a percentage of the amount by which actual expenditures exceeded expected expenditures. We proposed that we would require this percentage to exceed a required marginal risk percentage of 30 percent regardless of the amount by which actual expenditures exceeded expected expenditures. We believed that any marginal risk below 30 percent could create scenarios in which the total risk could be very high, but the average or likely risk for an APM Entity would actually be very low (81 FR 28306).

Our rationale for proposing the marginal risk requirement was that the inclusion of the marginal risk requirement would contribute to maintaining a more than nominal level of average or likely risk under an Advanced APM. We did not finalize the marginal risk requirement under the Advanced APM criteria because, as noted above, we believed that all Advanced APMs that we operate now or would potentially operate in the future would meet or exceed the previously proposed marginal risk and MLR requirements, and we believed the total risk portion of the nominal amount standard alone was sufficient to ensure that the level of average or likely risk under an Advanced APM would actually be more than nominal for participants.

However, based on our experience to date, we became concerned that the total risk portion of the benchmark-based nominal amount standard as currently constructed may not always be sufficient to ensure that the level of average or likely risk under an Advanced APM is actually more than nominal for participants. This is because the benchmark-based nominal amount standard at § 414.1415(c)(3)(i)(B) is dependent upon the definition of expected expenditures codified at § 414.1415(c)(5), where expected expenditures are defined as the beneficiary expenditures for which an APM Entity is responsible under an APM, and for episode payment models, the episode target price.

In our experience implementing the Quality Payment Program and considering the diversity of model designs, we came to believe there is a need to amend the definition of expected expenditures to further ensure there are more-than-nominal levels of average or likely risk under an Advanced APM that would meet the generally applicable benchmark-based nominal amount standard. For instance, an APM could have a sufficient total risk to meet the benchmark-based nominal amount standard and a sharing rate that results in adequate marginal risk if actual expenditures exceed expected expenditures. However, in that same APM, the level of expected expenditures reflected in the APM's benchmark or episode target price could be set in a manner that would substantially reduce the amount of loss the APM Entity would reasonably expect to incur.

For an APM to meet the generally applicable benchmark-based nominal amount standard, we believe there should be not only the potential for financial losses based on expenditures in excess of the benchmark as provided in § 415.1415(c)(3)(i)(B) of our regulations, but also a meaningful possibility that an APM Entity might exceed the benchmark. If the benchmark is set in such a way that it is extremely unlikely that participants would exceed it, then there is little potential for participants to incur financial losses, and the amount of risk is essentially illusory.

Therefore, in the CY 2020 PFS proposed rule (84 FR 40731 through 40732), we proposed to amend the definition of expected expenditures at § 414.1415(c)(5). Specifically, we proposed to define expected expenditures for purposes of this section as the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the terms of the APM should not exceed the expected Medicare Parts A and B expenditures for a participant in the absence of the APM. If expected expenditures under the APM exceed the Medicare Parts A and B

expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for Advanced APM determinations.

In general, expected expenditures are expressed as a dollar amount, and may be derived for a particular APM from national, regional, APM Entity-specific, and/or practice-specific historical expenditures during a baseline period, or other comparable expenditures. However, in making our proposal, we recognized that expected expenditures under an APM often are risk-adjusted and trended forward, and may be adjusted to account for expenditure changes that are expected to occur as a result of APM participation. For the purpose of the definition of expected expenditures that we proposed, we would not consider risk adjustments to be excess expenditures when comparing expected expenditures under the APM to the costs that an APM Entity would be expected to incur in the absence of the APM.

We proposed the amendment to the definition of expected expenditures to allow us to ensure that there are more-than-nominal amounts of average or likely risk under an APM that meets the generally applicable benchmark-based nominal amount standard. We also believed that the proposed amended definition of expected expenditures, particularly the proposal to not consider excess expenditures when determining whether an APM meets the benchmark-based nominal amount standard, would provide a more appropriate basis for us to assess whether an APM Entity would bear more than a nominal amount of financial risk for participants under the generally applicable benchmark-based nominal amount standard.

We also proposed a similar amendment to the definition of expected expenditures for the Other Payer Advanced APM generally applicable nominal amount standard in section III.I.4.d.(2)(b)(i) of this final rule.

We sought comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the proposed amended definition of expected expenditures. These commenters were concerned that application of the proposed definition of expected expenditures could potentially cause some current Advanced APMs to no longer meet the generally applicable nominal amount standard beginning in CY 2020, and thus to no longer be Advanced APMs.

Response: It is possible that application of the amended definition could lead to a current Advanced APM no longer meeting the expected expenditure nominal amount standard at § 414.1415(c)(3)(i)(B), and potentially no longer being an Advanced APM if it does not meet the standard at § 414.1415(c)(3)(i)(A). However, all Advanced APMs for CY 2019 that satisfy the current generally applicable nominal amount standard by meeting the expected expenditure nominal amount standard at § 414.1415(c)(3)(i)(B) would continue to do so under the proposed amended definition of expected expenditures.

Comment: A few commenters supported the exclusion of risk adjustment when considering what constitutes excess expenditures.

Response: We thank the commenters for their support of our proposal and will not consider risk adjustments to be excess expenditures when comparing expected expenditures under the APM to the costs that an APM Entity would be expected to incur in the absence of the APM.

After considering the public comments received, we are finalizing our proposal to amend the definition of expected expenditures at § 414.1415(c)(5) without modification.

(c) Excluded Items and Services Under Full Capitation Arrangements

In the CY 2017 Quality Payment Program final rule (81 FR 74431), we finalized a capitation standard at § 414.1415(c)(6), which provides that a full capitation arrangement meets the Advanced APM financial risk criterion. We defined a capitation arrangement as a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. We clarified that arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program are not considered capitation arrangements for purposes of this definition.

In the CY 2019 PFS final rule (83 FR 59939), we made technical corrections to the Advanced APM financial risk capitation standard at § 414.1415(c)(6). These corrections clarified that our financial risk capitation standard applies only to full capitation arrangements where a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement or reconciliation is performed.

As we began to collect information on other payer payment arrangements for purposes of making Other Payer Advanced APM determinations, we noticed that some payment arrangements that are submitted as capitation arrangements consistent with § 414.1420(d)(7) include a list of services that have been excluded from the capitation rate, such as hospice care, organ transplants, and out-of-network emergency services. In reviewing these exclusion lists, we came to believe that it may be appropriate for CMS to allow certain capitation arrangements to be considered ''full'' capitation arrangements even if they categorically exclude certain items or services from payment through the capitation rate.

As such, in the CY 2020 PFS proposed rule (84 FR 40827), we solicited comments on what categories of items and services might be excluded from a capitation arrangement that would still be considered a full capitation arrangement. Specifically, we solicited comment on whether there are common industry practices to exclude certain categories of items and services from capitated payment rates and, if so, whether there are common principles or reasons for excluding those categories of services. We also sought comment on what percentage of the total cost of care such exclusions typically account for under what is intended to be a ''full'' global capitation arrangement. We also solicited comment on how non-Medicare payers define or prescribe certain categories of services that are excluded from global capitation payment arrangements.

We received a few comments on this topic as summarized below.

Comment: All commenters were supportive of excluding certain items and services from the definition of full capitation arrangements for the purposes of the advanced APM financial risk criterion. They asserted that the exclusion of certain services from the definition of full capitation arrangements for purposes of the Advanced APM financial risk criterion would provide the ability to tailor different APMs to meet the needs of different payers and provider types. The commenters also identified specific items and services such as hospice care, emergency care, or specific high cost pharmaceuticals.

Response: We will take these comments into consideration as we consider possible proposals in future rulemaking.

(3) Summary

In this section, we are finalizing the following policy:

• *Expected Expenditures:* We are finalizing as proposed an amendment to the definition of expected expenditures at § 414.1415(c)(5) to state that for the purposes of this section, for purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the terms of the APM should not exceed the expected Medicare Parts A and B expenditures for a participant in the absence of the APM. If expected expenditures under the APM exceed the Medicare Parts A and B expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for Advanced APM determinations.

d. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450), we finalized policies relating to QP and Partial QP determinations. In the CY 2019 PFS final rule (83 FR 59923 through 59925), we finalized additional policies relating to QP determinations and the Partial QP election to report to MIPS.

(2) Group Determination

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77440), we finalized that QP determinations would generally be made at the APM Entity level, but for two exceptions in which we make the QP determination at the individual level: (1) Individuals participating in multiple Advanced APM Entities, none of which meet the QP threshold as a group; and (2) eligible clinicians on an Affiliated Practitioner List when that list is used for the QP determination because there are no eligible clinicians on a Participation List for the APM Entity (81 FR 77439 through 77443). As a result, the QP determination for the APM Entity generally applies to all the individual eligible clinicians who are identified as part of the APM Entity participating in an Advanced APM. If the APM Entity's Threshold Score meets the relevant QP threshold, all individual eligible clinicians in that APM Entity would receive the same QP determination, applied to their NPIs, for the relevant payment year. The QP determination calculations are aggregated using data for all eligible clinicians participating in the APM Entity on a determination date during the QP Performance Period.

(b) Application of Partial QP Status

In the CY 2017 Quality Payment Program final rule (81 FR 77440), we stated that we would apply QP status at the NPI level instead of at the TIN/NPI level. We noted that an individual clinician identified by an NPI may have reassigned billing rights to multiple TINs, resulting in multiple TIN/NPI combinations being associated with one individual clinician (NPI). We also stated that if QP status was only applied to one of an individual clinician's multiple TIN/NPI combinations, an eligible clinician who is a QP for only one TIN/NPI combination might still have to report under MIPS for another TIN/NPI combination. Under that approach, the APM Incentive Payment would be based on only a fraction of the clinician's covered professional services instead of, as we believe is the most logical reading of the statute, all those services furnished by the individual clinician, as represented by an NPI. Therefore, we expressed our concern with applying QP status only to a specific TIN/NPI combination as it would not effectuate the goals of the APM incentive path of the Quality Payment Program to reward individual clinicians for their commitment to Advanced APM participation.

For Partial QPs, we currently apply Partial QP status at the NPI level across all TIN/NPI combinations as we have for QP status. However, in the CY 2020 PFS proposed rule (84 FR 40827 through 40828), we explained that for eligible clinicians who are Partial QPs, based on our experience implementing the Quality Payment Program and feedback from stakeholders, we believe it would be more appropriate to apply any exclusion from MIPS reporting requirements and payment adjustments only to TIN/NPI combinations affiliated with that TIN. Under our current policy, Partial QPs are excluded from the MIPS reporting requirements and payment adjustment based on an election made at the APM Entity or individual eligible clinician level, and this exclusion is currently applied at the NPI level across all of their TIN/NPI combinations. Partial QPs do not receive an APM Incentive Payment; rather, the APM Entity in which the Partial QPs participated is permitted to choose whether to be subject to the MIPS reporting requirements and payment adjustments. As such, while an eligible clinician who is a Partial QP might wish to be excluded from MIPS reporting requirements and payment adjustments with respect to the TIN/NPI combination that relates to the APM Entity in the Advanced APM through which they achieved Partial QP status, that same eligible clinician might wish to report to MIPS and receive a MIPS payment adjustment with respect to other TIN/NPI combinations (for example, because they anticipate receiving an upward MIPS payment adjustment).

Therefore, we proposed that beginning with the 2020 QP Performance Period, Partial QP status would apply only to the TIN/NPI combination(s) through which an individual eligible clinician attains Partial QP status, and to amend our regulation by adding § 414.1425(d)(5) to reflect this change. This means that any MIPS election for a Partial QP would only apply to the TIN/NPI combination through which Partial QP status is attained, so that an eligible clinician who is a Partial QP for only one TIN/NPI combination may still be a MIPS eligible clinician, and subject to the MIPS reporting requirements and payment adjustment, for other TIN/NPI combinations.

We received public comments on our proposal. We thank the commenters for the public comments on this proposal. After including our proposal in the CY 2020 PFS proposed rule (84 FR 40827 through 40828), we further investigated the system requirements to implement the proposed policy. Our current data systems apply Partial QP assignment to NPIs, rather than to TIN/NPI combinations, and we determined that we would not be able to modify our system to implement the proposed policy, if finalized, for the 2020 QP Performance Period. After taking into account our operational limitations, we are not finalizing the proposed policy. We will review and consider the public comments received, continue to seek stakeholder feedback and, if appropriate, proposed policies pertaining to Partial QPs in future rulemaking.

(3) QP Performance Period

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77446 through 77447), we finalized for the timing of QP determinations that a QP Performance Period runs from January 1 through August 31 of the calendar year that is 2 years prior to the payment year. We finalized that during the QP Performance Period, we will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31), each of which will be a final determination for the eligible clinicians

who are determined to be QPs. The QP Performance Period and the three separate QP determinations apply similarly for both the group of eligible clinicians on a Participation List and the individual eligible clinicians on an Affiliated Practitioner List.

(b) APM Entity Termination

In the CY 2017 Quality Payment Program final rule, we finalized at §§ 414.1425(c)(5) and 414.1425(d)(3) that an eligible clinician is not a QP or Partial QP for a year if the APM Entity group voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period (81 FR 77446 through 77447). We also finalized at §§ 414.1425(c)(6) and 414.1425(d)(4) that an eligible clinician is not a QP or Partial QP for a year if one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP or Partial QP payment amount threshold or QP or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities (81 FR 77446 through 77447). We finalized these policies in part to ensure that APM Entities and eligible clinicians who achieve QP or Partial QP status during a QP Performance Period actually assume a more than a nominal amount of financial risk, as is necessary for Advanced APMs, for at least the full QP performance period from January 1 through August 31, if not the entire performance year under the Advanced APM.

Currently, under the terms of some Advanced APMs, APM Entities can terminate their participation in the Advanced APM while bearing no financial risk after the end of the QP Performance Period for the year (August 31). Under our current regulation, an APM Entity's termination after that date would not affect the QP or Partial QP status of all eligible clinicians in the APM Entity. In the CY 2020 PFS proposed rule (84 FR 40828), we acknowledged that it may be appropriate for an Advanced APM to allow participating APM Entities to terminate without bearing financial risk for that performance period under the terms of the Advanced APM itself, including allowing such terminations to occur after the end of the QP Performance Period (August 31). However, we noted that allowing those eligible clinicians to retain their QP or Partial QP status without having borne financial risk under the Advanced APM through which they attained QP or Partial QP status is not aligned with the structure and principles of the Quality Payment Program, which is designed to reward those APM Entities and eligible clinicians for meaningfully assuming more than a nominal amount of financial risk, as required by the Advanced APM criteria. A critical aspect of Advanced APMs is that participants must bear more than a nominal amount of financial risk under the model. If an APM Entity terminates participation in the Advanced APM without financial accountability, the APM Entity has not yet borne more than a nominal amount of financial risk. As such, we do not believe it is appropriate for eligible clinicians in an APM Entity that terminates after QP determinations are made, but before bearing more than a nominal amount of financial risk, to retain any status as QPs or Partial QPs.

Therefore, regarding QP status, in the CY 2020 PFS proposed rule (84 FR 40827 through 40828), we proposed to revise our regulation at § 414.1425(c)(5) and to add § 414.1425(c)(5)(i) and (ii) to state, beginning with the 2020 QP Performance Period, that an eligible clinician is not a QP for a year if: (1) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; (2) or the APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. In addition, we proposed to revise our regulation at § 414.1425(c)(6) and add §§ 414.1425(c)(6)(i) and (ii) to state, beginning with the 2020 QP Performance Period, that an eligible clinician is not a QP for a year if: (1) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or (2) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities.

Regarding Partial QP status, in the CY 2020 PFS proposed rule (84 FR 40828), we also proposed to revise § 414.1425(d)(3) and add §§ 414.1425(d)(3)(i) and (ii), to state, beginning with the 2020 QP Performance Period, that an eligible clinician is not a Partial QP for a year if: (1) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or (2) the APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. We also proposed to revise § 414.1425(d)(4) and add §§ 414.1425(d)(4)(i) and (ii), to state, beginning with the 2020 QP Performance Period, that an eligible clinician is not a Partial QP for a year if: (1) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities; or (2) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities. We believe these amendments and additions account for the scenarios in which an APM Entity could terminate from an Advanced APM at a date on which the APM Entity would not incur any financial accountability under the terms of the Advanced APM.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed our proposal. A few of these commenters agreed that QPs in APM Entities that terminated their

participation in an Advanced APM without bearing financial risk should not receive the APM Incentive Payment. These commenters expressed concern that there would be a very short window of time between the termination from the Advanced APM and the reporting deadlines required for reporting to MIPS such that there would not be enough time to prepare for MIPS reporting for that year.

Response: We have consistently maintained that participants in Advanced APMs may be considered MIPS eligible clinicians and that they may need to report to MIPS, depending on whether they attain QP or Partial QP status. Eligible clinicians who participate with one or more APM Entities in Advanced APMs are MIPS eligible clinicians unless they are excluded from MIPS based on QP or Partial QP status, or some other ground. As such, they are potentially subject to the MIPS reporting requirements and payment adjustment throughout the performance year. We encourage individual eligible clinicians who are Advanced APM participants to check their QP or Partial QP status throughout the year online, and to communicate with their APM Entities in case there are any changes at the APM Entity Level that may affect whether they will need to report to MIPS.

Comment: One commenter suggested that for involuntary terminations, of an APM Entity's participation in an Advanced APM, affected eligible clinicians should retain their QP or Partial QP status based on their significant investment and participation in the Advanced APM.

Response: We acknowledge that participation in Advanced APMs is a significant investment. However, we also recognize that opportunities exist to take advantage of the program. Whether termination is voluntary or involuntary, we have a duty to ensure that the benefits of QP or Partial QP status, including the APM Incentive Payment and any exemption from the MIPS reporting requirements and payment adjustment is based on fully meeting the elements of Advanced APM participation, including the requirement that an APM Entity in an Advanced APM is actually required to bear a more than nominal amount of financial risk during the relevant QP Performance Period.

We are finalizing our proposed policies without modification that an eligible clinician is not a QP or a Partial QP for the year through an APM Entity that voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity will not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs.

(4) Summary

In this section, we are taking the following actions on our proposed policies:

- *Application of Partial QP Status:* We are not finalizing our proposal that, beginning with the 2020 QP Performance Period, Partial QP status will apply only to the TIN/NPI combination(s) through which an individual eligible clinician attains Partial QP status.
- *APM Entity Termination:* We are finalizing without modification the proposal to revise our regulations at §§ 414.1425(c)(5) and (6) and (d)(3) and (4) to state that an eligible clinician is not a QP or a Partial QP for the year when an APM Entity terminates voluntarily or involuntarily from an Advanced APM at a date on which the APM Entity will not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs.

e. All-Payer Combination Option

(1) Overview

Section 1833(z)(2)(B)(ii) of the Act requires that beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the Combination All-Payer and Medicare Payment Threshold Option, which we refer to as the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule (81 FR 77459), we finalized our overall approach to the All-Payer Combination Option. The Medicare Option focuses on participation in Advanced APMs, and we make QP determinations under this option based on Medicare Part B covered professional services attributable to services furnished through an APM Entity. The All-Payer Combination Option does not replace or supersede the Medicare Option; instead, it will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through payment arrangements offered by payers other than Medicare that CMS has determined meet the criteria to be Other Payer Advanced APMs. We finalized that beginning in payment year 2021, we will conduct QP determinations sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77438). The All-Payer Combination Option encourages eligible clinicians to participate in payment arrangements that satisfy the Other Payer Advanced APM criteria with payers other than Medicare. It also encourages sustained participation in Advanced APMs across multiple payers.

We finalized that the QP determinations under the All-Payer Combination Option are based on payment amounts or patient counts as illustrated in Tables 36 and 37, and Figures 1 and 2 of the CY 2017 Quality Payment Program final rule (81 FR 77460 through 77461), presented in this final rule as Tables 64A and 64B and Figures 2 and 3. We also finalized that, in making QP determinations with respect to an eligible clinician, we will use the Threshold Score (that is, based on payment amount or patient count) that is most advantageous to the eligible clinician toward achieving QP status, or if QP status is not achieved, Partial QP status, for the year (81 FR 77475).

TABLE 64A: QP Payment Amount Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	25%	25%	25%
Total			50%	50%	75%
Partial QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			40%	40%	50%

TABLE 64B: QP Patient Count Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			35%	35%	50%
Partial QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	10%	10%	10%
Total			25%	25%	35%

FIGURE 2: QP Determination Tree, Payment Years 2021-2022

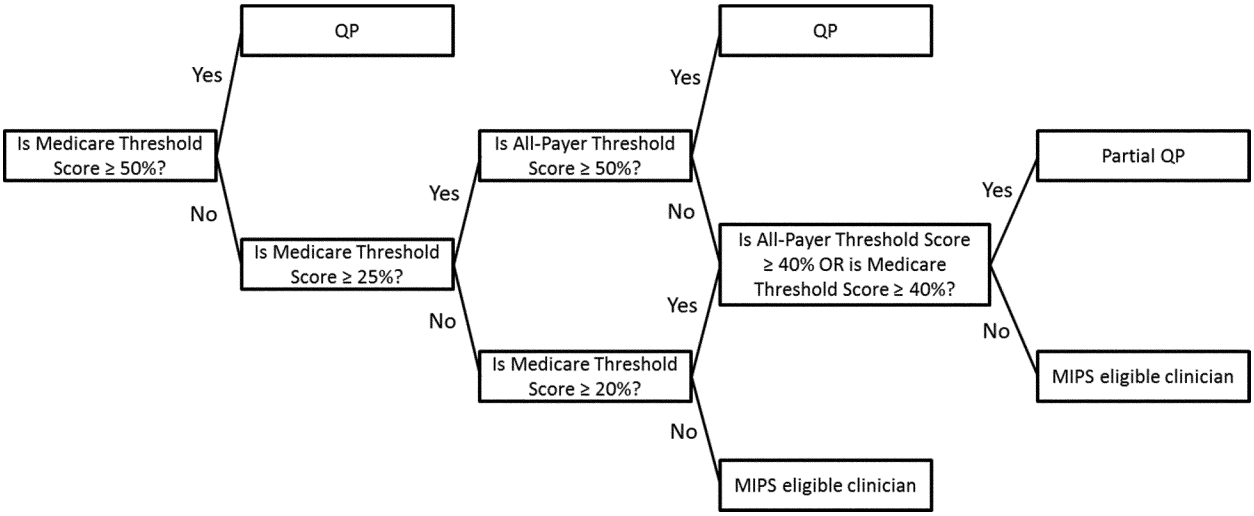
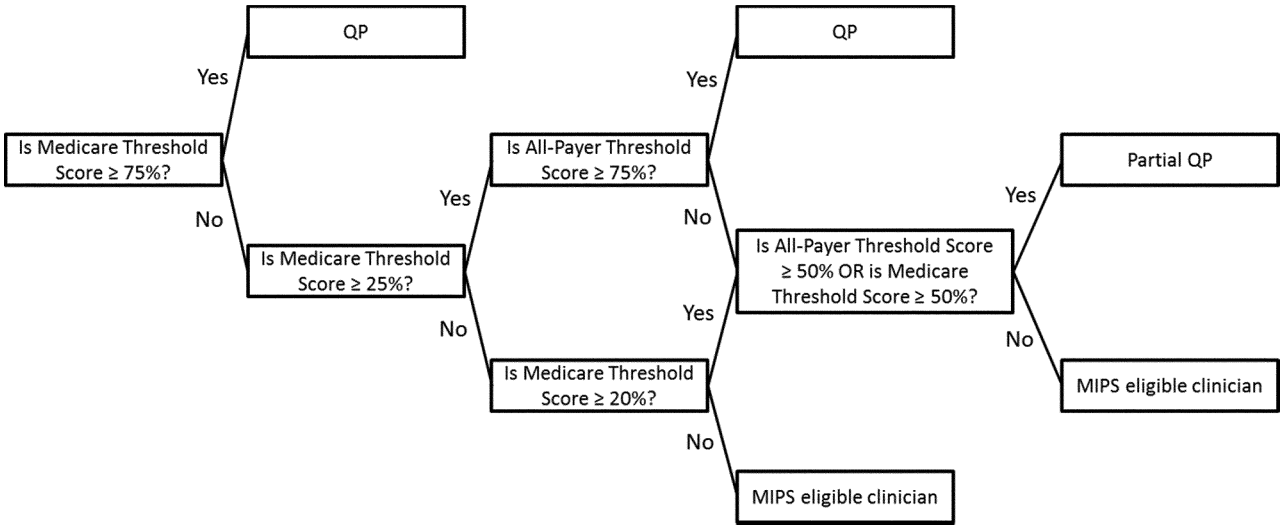


FIGURE 3: QP Determination Tree, Payment Years 2023 and Later



Unlike the Medicare Option where we have access to all of the information necessary to determine whether an APM meets the criteria to be an Advanced APM, we cannot determine whether payment arrangements offered by other payers meet the criteria to be an Other Payer Advanced APM without receiving information about the payment arrangements from an external source. Similarly, we do not have the necessary payment amount and patient count information to determine under the All-Payer Combination Option whether an eligible clinician meets the payment amount or patient count threshold to be a QP without receiving certain information from an external source.

In the CY 2018 Quality Payment Program final rule (82 FR 53844 through 53890), we established additional policies to implement the All-Payer Combination Option and finalized certain modifications to our previously finalized policies. A detailed summary of those policies can be found at 82 FR 53874 through 53876 and 53890 through 53891.

In the CY 2019 PFS final rule (83 FR 59926 through 59938), we finalized the following:

Other Payer Advanced APM Criteria

- We changed the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each participating APM Entity group, or each hospital if hospitals are the APM Entities, use CEHRT to document and communicate clinical care.
- We allowed payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care; and specified that we will use such evidence to demonstrate the level of CEHRT use, whether or not CEHRT use is explicitly required under the terms of the payment arrangement.
- We amended § 414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

- We revised § 414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, that to be an Other Payer Advanced APM, an other payer arrangement must use an outcome measure, that must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

- We also revised our regulation at § 414.1420(c)(3)(i) to provide that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year that did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as finalized in CY 2019 PFS final rule (83 FR 55931 through 55932), we would continue to apply the previous requirements for purposes of those determinations. This revision also applies to payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.
- We revised § 414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

Determination of Other Payer Advanced APMs

- We finalized details regarding the Payer Initiated Process for Remaining Other Payers. To the extent possible, we aligned the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.
- We eliminated the Payer Initiated Process that is specifically for CMS Multi-Payer Models. These payers will be able to submit their arrangements through the Payer Initiated Process for Remaining Other Payers as finalized in the CY 2019 PFS final rule (82 FR 59933 through 59935), or through the Medicaid or Medicare Health Plan

payment arrangement submission processes, and no longer need a special pathway.

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

- We added a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We modified our regulation at § 414.1440(d) by adding a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.
- We clarified that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We codified this clarification by amending § 414.1440(d)(1).
- We extended the weighting methodology that is used to ensure that an eligible clinician does not receive a lower score on the Medicare portion of their all-payer calculation under the All-Payer Combination Option than the Medicare Threshold Score they received at the APM Entity level in order to apply a similar policy to the proposed TIN level Medicare Threshold Scores.

In this section of the final rule, we are finalizing our proposed definition of the term Aligned Other Payer Medical Home Model. We are also finalizing our proposals regarding bearing financial risk for monetary losses, specifically the Medicaid Medical Home Model financial risk standard and our proposed amendment to the definition of expected expenditures. We also discuss our request for comment on whether certain items and services could be excluded from the capitation rate consistent with our definition of full capitation arrangements.

(2) Aligned Other Payer Medical Home Models

(a) Definition

As we explained when finalizing the definitions of Medical Home Model and Medicaid Medical Home Model in the CY 2017 Quality Payment Program final rule, MACRA does not define ''medical homes,'' but sections 1848(q)(5)(C)(i), 1833(z)(2)(B)(iii)(II)(cc)(BB), 1833(z)(2)(C)(iii)(II)(cc)(BB), and 1833(z)(3)(D)(ii)(II) of the Act make medical homes an instrumental piece of the law (81 FR 77403). The terms Medical Home Model and Medicaid Medical Home Model are limited to Medicare and Medicaid payment arrangements, respectively, and do not include other payer payment arrangements.

As we discuss in section III.I.4.b. of this final rule, in the CY 2020 PFS proposed rule (84 FR 40832), we proposed to amend § 414.1305 to add the defined term ''Aligned Other Payer Medical Home Model'', which would mean an aligned other payer payment arrangement (not including a Medicaid payment arrangement) operated by an other payer formally partnering in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation with CMS, such as a memorandum of understanding (MOU), and is determined by CMS to have the following characteristics:

- The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;
- Empanelment of each patient to a primary clinician; and
- At least four of the following: Planned coordination of chronic and preventive care; Patient access and continuity of care; risk-stratified care management; coordination of care across the medical neighborhood; patient and caregiver engagement; shared decision-making; and/or payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

The proposed definition of Aligned Other Payer Medical Home Model includes the same characteristics as the definitions of Medical Home Model and Medicaid Medical Home Model, but it applies to other payer payment arrangements. In the CY 2020 PFS proposed rule (84 FR 40832), we explained that we believe that structuring this definition in this manner is appropriate because we recognize that there may be medical homes that are operated by other payers that may be appropriately considered medical home models under the All-Payer Combination Option.

We proposed to exclude Medicaid payment arrangements from this definition of Aligned Other Payer Medical Home Model because we have previously defined the term Medicaid Medical Home Model at § 414.1305 and we believe it is important to distinguish Medicaid payment arrangements from other payment arrangements, given the requirements in sections 1833(z)(2)(B)(ii)(I)(bb) and 1833(z)(3)(B)(ii)(I)(bb) of the Act requiring us to consider whether there is a medical home or alternative payment model under the Title XIX state plan in each state when making QP determinations using the All-Payer Combination Option.

For purposes of the Aligned Other Payer Medical Home Model definition, for an arrangement to be aligned, we explained that we mean through a written expression of alignment and cooperation with CMS, such as an MOU. CMS Multi-Payer Models require alignment across the different payers, and a written expression reflects the fact that each arrangement has been reviewed by CMS and CMS has determined that the other payer payment arrangement is aligned with a CMS Multi-Payer Model that is a Medical Home Model. We proposed to limit this Aligned Other Payer Medical Home Model definition to other payer payment arrangements that are aligned with CMS Multi-Payer Models that are Medical Home Models because we can be assured that the structure of these arrangements is similar to the Medical Home Models and Medicaid Medical Home Models for which we have already made a similar determination. Based on our experience to date, we anticipate that participants in these arrangements may generally be more limited in their ability to bear financial risk than other entities because they may be smaller and predominantly include primary care practitioners, whose revenues are a smaller fraction of the patients' total cost of care than those of other eligible clinicians. At the same time, we do not believe that participants in all medical homes, regardless of payer, face the same limitations on their ability to bear financial risk. We explained that we believe that some participants may have different organizational or financial circumstances that allow them to bear greater such risk. We believe that applying the proposed Aligned Other Payer Medical Home Model definition to all other payer payment arrangements

would create potential new opportunities for gaming in commercial settings where we do not have control over the design of such models. However, we believe that payment arrangements that have been aligned and are similar to a Medicaid Home Model, where we have already put in place policies to control against gaming, would be similarly constrained.

In addition, we have acquired additional understanding of some other payer payment arrangements after one year of experience with the Payer Initiated Process, which included some arrangements that are aligned with CMS Multi-Payer Models that are Medical Home Models.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposed definition of the term Aligned Other Payer Medical Home Model.

Response: We appreciate the support for adding the defined term Aligned Other Payer Medical Home Model.

Comment: Some commenters expressed concern that the proposed definition of Aligned Other Payer Medical Home Models would include only those other payer payment arrangements that meet the definition as proposed, requiring alignment with CMS Multi-Payer Models, and not including other payer payment arrangements that are not aligned with a CMS Multi-Payer Model. These commenters recommend that the definition be broadened to include any other payer payment arrangement that would not be formally partnering with a CMS Multi-Payer Model, but would otherwise meet the proposed definition. These commenters stated that CMS is being too prescriptive, and limiting the definition would unnecessarily limit opportunities for participation by eligible clinicians in other payer payment arrangements that would have all of the characteristics of medical home models. Some of these same commenters stated that, while they understood CMS' concern with potential gaming related to payment arrangements that have lower nominal risk thresholds, they believe CMS is already collecting sufficient information to allow for monitoring of other payer payment arrangements such that limiting the definition to only include other payer arrangements that are aligned with CMS Multi-Payer Models is not necessary. One commenter stated that CMS has generally attempted to align Advanced APM and Other Advanced APM policies, and asserted that approach should carry over to inclusion of all commercial payment arrangements that meet the Medical Home Model definition.

Response: We continue to be concerned about the potential for gaming associated with payment arrangements where we do not have any control over the design. We necessarily rely on a limited set of self-reported information, and as a result, we have a limited capability to monitor for, or respond effectively to, potential gaming. We also believe our cautious approach is appropriate given that the All-Payer Combination Option has only been available since the 2019 QP Performance Period and we are still gathering additional information and experience. We acknowledge that limiting the definition of Aligned Other Payer Medical Home Model to only include other payer payment arrangements that meet the proposed definition, including alignment with a CMS Multi-Payer Model, may result in some other payer payment arrangements not being considered an Aligned Other Payer Medical Home Model even though they may be structurally similar to Medical Home Models and Medicaid Medical Home Models. However, as we discussed in the CY 2020 PFS proposed rule (84 FR 40833), we continue to believe that finalizing the definition as proposed is the best approach for expanding innovation while ensuring program integrity.

After considering public comments, we are finalizing without modification our proposal to amend § 414.1305 to define the term ''Aligned Other Payer Medical Home Model''.

(b) Other Payer Advanced APM Criteria for Aligned Other Payer Medical Home Models

As defined in § 414.1305, an Other Payer Advanced APM is an other payer arrangement that meets the Other Payer Advanced APM criteria set forth in § 414.1420. Accordingly, in the CY 2020 PFS proposed rule (84 FR 40833), we proposed that the CEHRT criterion codified in § 414.1420(b) and the use of quality measures criterion codified in § 414.1420(c) will apply to any Aligned Other Payer Medical Home Model for which we will make an Other Payer Advanced APM determination. Further, we proposed to revise § 414.1420(d)(8) to require Aligned Other Payer Medical Home Models to comply with the 50 eligible clinician limit to align with the requirements that apply to Medical Home Models and Medicaid Medical Home Models.

Regarding the applicable financial risk and nominal amount standards, consistent with the financial risk and nominal amount standards applicable to Medical Home Models and Medicaid Medical Home Models, we proposed that the Aligned Other Payer Medical Home Model financial risk and nominal amount standards will be the same as the Medicaid Medical Home Model financial risk and nominal amount standards. We proposed corresponding amendments to § 414.1420(d)(2) and (4) so that those sections would reflect the Medicaid Medical Home Model and Aligned Other Payer Medical Home Model financial risk standard, and Medicaid Medical Home Model and Aligned Other Payer Medical Home Model nominal amount standard, respectively. We proposed this policy consistent with our principle of aligning the Advanced APM criteria and Other Payer Advanced APM criteria to the extent feasible and appropriate, as well as our continued belief that organization size is a proxy for potential risk-bearing capacity.

We did not receive any public comments on our proposal that the CEHRT criterion in § 414.1420(b) and the use of quality measures criterion in § 414.1420(c) will apply to any Aligned Other Payer Medical Home Model for which we will make an Other Payer Advanced APM determination. We discuss public comments regarding our proposal to apply the 50 eligible clinician limit to Aligned Other Payer Medical Home Models in section III.K.4.e.(3)(b) of this final rule.

We are finalizing without modification our proposal that the CEHRT criterion codified in § 414.1420(b) and the use of quality measures criterion codified in § 414.1420(c) will apply to any Aligned Other Payer Medical Home Model for which we will make an Other Payer Advanced APM determination.

(c) Determination of Aligned Other Payer Medical Home Model and Other Payer Advanced APM Status

In the CY 2020 PFS proposed rule (84 FR 40833), we proposed that payers may submit other payer arrangements for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Payer Initiated Process, to be effective January 1, 2020, for applications for the 2021 QP Performance Period. In the CY 2019 PFS final rule, we finalized a process for Remaining Other Payers to submit other payer arrangements for CMS determination of Other Payer Advanced APM status (83 FR 59934 through 59935). Other payers will be required to submit their other payer arrangements

for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, using this Remaining Other Payer process.

We also proposed that APM Entities and eligible clinicians can submit other payer arrangements for CMS to determine whether they are Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Eligible Clinician Initiated Process.

We received no public comments on these proposals. We are finalizing our proposal without modification that payers may submit other payer arrangements for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Payer Initiated Process. This policy will be effective January 1, 2020, beginning with applications submitted for the 2021 QP Performance Period. Other payers will submit their other payer arrangements for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, using this Remaining Other Payer process. We are also finalizing our proposal without modification that APM Entities and eligible clinicians can submit other payer arrangements for CMS to determine whether they are Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Eligible Clinician Initiated Process.

(3) Bearing Financial Risk for Monetary Losses

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77466), we divided the discussion of this criterion into two main topics: (1) What it means for an APM Entity to bear financial risk if actual aggregate expenditures exceed expected aggregate expenditures under a payment arrangement (which we refer to as either the generally applicable financial risk standard or Medicaid Medical Home Model financial risk standard); and (2) what levels of risk we would consider to be in excess of a nominal amount (which we refer to as either the generally applicable nominal amount standard or the Medicaid Medical Home Model nominal amount standard).

In the CY 2017 Quality Payment Program final rule, we finalized that for a Medicaid Medical Home Model to be an Other Payer Advanced APM, if the APM Entity's actual aggregate expenditures exceed expected aggregate expenditures, the Medicaid Medical Home Model must:

- Withhold payment for services in the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians;
- Require direct payment by the APM Entity to the Medicaid program; or
- Require the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

We based this standard on our belief that Medicaid Medical Home Models are unique types of Medicaid APMs because they are identified and treated differently under the statute. We believe it is appropriate to establish a unique standard for bearing financial risk that reflects these statutory differences and remains consistent with the statutory scheme, which is to provide incentives for participation by eligible clinicians in Advanced APMs (81 FR 77467 through 77468).

In addition, to be an Other Payer Advanced APM, a Medicaid Medical Home Model must require that the total annual amount that an APM Entity potentially owes or foregoes under the Medicaid Medical Home Model must be at least:

- For QP Performance Period 2019, 3 percent of the APM Entity's total revenue under the payer.
- For QP Performance Period 2020, 4 percent of the APM Entity's total revenue under the payer.
- For QP Performance Period 2021 and later, 5 percent of the APM Entity's total revenue under the payer.

(b) Aligned Other Payer Medical Home Model Financial Risk and Nominal Amount Standards

Neither the current Medical Home Model financial risk and nominal amount standards nor the Medicaid Medical Home Model financial risk and nominal amount standards apply to similar arrangements with other payers for purposes of Other Payer Advanced APM determinations. Consistent with the proposal we are finalizing in this rule to define the term, Aligned Other Payer Medical Home Model. In the CY 2020 PFS proposed rule (84 FR 40834), we proposed to amend § 414.1420(d)(2) and (d)(4) of our regulations to conform the financial risk and nominal amount standards for Aligned Other Payer Medical Home Models with the existing Medicaid Medical Home Model financial risk and nominal amount standards. Recognizing the similar characteristics of these ''medical home'' other payer payment arrangements, we believe that the same financial risk and nominal amount standards should be applied to Aligned Other Payer Medical Home Models as to Medicaid Medical Home Models.

Further, we proposed a corresponding amendment to § 414.1420(d)(2)(ii) to state that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, an Aligned Other Payer Medical Home Model must require the direct payment by the APM Entity to the payer. This amendment would further conform the requirements for Aligned Other Payer Medical Home Models with the current requirements for Medicaid Medical Home Models.

We explained that we believe that if we applied the Medicaid Medical Home Model financial risk and nominal amount standards to all other payer arrangements that would meet the Aligned Other Payer Medical Home Model definition, but for the arrangements' not being aligned with a CMS Multi-Payer Model that is a Medical Home Model, we might create gaming opportunities whereby other payers might develop arrangements that appear to be medical homes solely to take advantage of the unique nominal amount standard. This would be of particular concern because we have less insight into the nature of arrangements not aligned with CMS Multi-Payer Models.

In addition, as the 50 eligible clinician limit as codified in §§ 414.1415(c)(7) and 414.1420(d)(8) currently applies to Medical Home Models and Medicaid Medical Home Models, respectively, we correspondingly proposed that the 50 eligible clinician limit apply to Aligned Other Payer Medical Home Models by amending § 414.1420(d)(8).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposed amendment to our regulations to conform the financial risk and nominal amount standards for Aligned Other Payer Medical Home Models with those for Medicaid Medical Home Models.

Response: We appreciate the commenters' support for our proposal.

Comment: A few commenters supported our proposal to make corresponding revisions to § 414.1420(d)(2)(ii) to add that an Aligned Other Payer Medical Home Model must require the direct payment by the APM Entity to the payer, aligning with the current requirement for Medicaid Medical Home Models.

Response: We appreciate the commenters' support for our proposal.

Comment: Two commenters opposed our proposal to require Aligned Other Payer Medical Home Models to comply with the 50 eligible clinician limit to align with the requirements that apply to Medical Home Models and Medicaid Medical Home Models. These commenters stated that the application of the 50 eligible clinician limit to Aligned Other Payer Medical Home Models is an arbitrary cap that would unnecessarily limit the adoption of such payment arrangements by excluding certain entities and clinicians who would benefit from participating in an Aligned Other Payer Medical Home Model. Specifically, the commenters expressed concern that certain large specialty groups would be unable to participate in Aligned Other Payer Medical Home Models if the 50 eligible clinician limit were finalized.

Response: As a general principle, we align policies pertaining to the Advanced APM criteria and the Other Payer Advanced APM criteria to the extent feasible and appropriate. We continue to believe that alignment of the requirements that apply to Medical Home Models, Medicaid Medical Home Models, and Aligned Other Payer Medical Home Models, including the 50 eligible clinician limit, is appropriate.

After considering public comments, we are finalizing our proposal, without modification, to amend § 414.1420(d)(2) and (4) to conform the financial risk and nominal amount standards for Aligned Other Payer Medical Home Models with the existing Medicaid Medical Home Model financial risk and nominal amount standards for Medicaid Medical Home Models as proposed. We are also finalizing without modification our proposal that the 50 eligible clinician limit apply to Aligned Other Payer Medical Home Models by amending § 414.1420(d)(8).

(b) Generally Applicable Other Payer Advanced APM Nominal Amount Standard

(i) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77471), we finalized at § 414.1420(d)(3)(ii) that except for risk arrangements described under the Medicaid Medical Home Model Standard, for a payment arrangement to meet the nominal amount standard, the specific level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures and total potential risk must be at least 4 percent of the expected expenditures. Furthermore, we finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement. Section 414.1420(d)(6) provides that, for purposes of this section, expected expenditures is defined as the Other Payer Advanced APM benchmark or, for episode payment models, as the episode target price.

(ii) Marginal Risk

As we stated in the 2017 Quality Payment Program final rule (81 FR 77470), to determine that a payment arrangement satisfies the marginal risk portion of the nominal amount standard, we would examine the payment required under the payment arrangement as a percentage of the amount by which actual expenditures exceeded expected expenditures. Specifically, for marginal risk we finalized that for a payment arrangement to meet the nominal amount standard, the specific level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures. We also stated that the rate of marginal risk could vary with the amount of losses.

To date, we have applied the marginal risk requirement as requiring that a payment arrangement must exceed the marginal risk rate of 30 percent at all levels of total losses even as the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, consistent with § 414.1420(d)(5)(i). For example, certain other payer arrangements where the marginal risk met or exceeded 30 percent at lower levels of losses in excess of expected expenditures, but fell below 30 percent at higher levels of losses, would not meet the marginal risk requirement of the generally applicable nominal amount standard.

In general, this approach has worked well and served its intended purpose of ensuring only other payer arrangements with strong financial risk components are determined to be Other Payer Advanced APMs. At the same time, this policy has necessitated that we determine that certain other payer arrangements are not Other Payer Advanced APMs even though they include strong financial risk components and well exceed the 30 percent marginal risk requirement at the most common levels of losses in excess of expected expenditures, and employ marginal risk rates below 30 percent only at much higher levels of losses. We do not believe these other payer arrangements include marginal risk rates below 30 percent to avoid subjecting participants to more than nominal amounts of risk. Rather, we believe that these other payer arrangements employ the lower marginal risk rates at higher levels of losses in order to protect participants from potentially catastrophic losses and undue financial burden that might arise because of market factors likely outside their control.

Therefore, in the CY 2020 PFS proposed rule (84 FR 40834), we proposed to amend § 414.1420(d)(5)(i) to provide that in event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, we would use the average marginal risk rate across all possible levels of actual expenditures for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of this section, with exceptions for large losses and small losses as described in paragraphs (d)(5)(ii) and (d)(5)(iii) of this section.

We proposed that we would calculate the average marginal risk rate in two steps. An example of such a calculation is presented in Table 65. This example uses a model that relies on a Total Cost of Care (TCOC) benchmark. This methodology for the calculating average marginal risk rate can also be applied to other types of other payer payment arrangements. In this example, we first take the sum of the marginal risk for each percent above the Total Cost of Care (TCOC) benchmark to determine the participant losses. For example, at 3 percent add 50 percent (amount for 1 percent above benchmark) plus 50 percent (amount for 2 percent above benchmark) plus 50 percent (amount for 3 percent above benchmark), which equals 1.50 percent. Second, we divide the participant losses by the percentage above the benchmark (in our example, 1.50 percent divided by 3) to get average marginal risk. The average marginal risk rate remains above 30 percent at all levels of potential losses up to the point where the participant would be responsible for losses equal to the total potential risk requirement of 3 percent. We note that this example presents the calculation only up to the point where the total potential risk requirement is met.

TABLE 65: Example Average Marginal Risk Calculation

Performance (% above TCOC Benchmark)	Marginal Risk	Participant Losses	Average marginal risk
1%	50%	0.50%	50%
2%	50%	1.00%	50%
3%	50%	1.50%	50%
4%	25%	1.75%	44%
5%	25%	2.00%	40%
6%	25%	2.25%	38%
7%	25%	2.50%	36%
8%	25%	2.75%	34%
9%	25%	3.00%	33%

As we discussed in the CY 2020 PFS proposed rule (84 FR 40835), with this proposed amendment, significant and meaningful financial risk would continue to be required for Other Payer Advanced APMs because the average marginal risk rate would need to be at least 30 percent. At the same time, the proposed amendment would allow us to recognize that significant and meaningful risk can be present even where there is wide variation in the application of marginal risk rates, allowing for continued innovation in the marketplace. This proposed policy is intended to ensure that all Other Payer Advanced APMs include marginal risk of at least 30 percent up to the point that the participant owes 3 percent of losses, which is the intended effect of the current marginal risk standard, while providing flexibility to avoid excluding certain payment arrangements that have strong financial risk designs. When considering average marginal risk in the context of total risk, as we propose to do for Other Payer Advanced APM determinations, certain risk arrangements can create meaningful and significant risk-based incentives for performance and at the same time ensure that the payment arrangement has strong financial risk components.

We note that in making this change we would not lower the standard for the applicable marginal risk rate, but rather allow for new flexibility as to how it can be met. In the CY 2020 PFS proposed rule, we clarified that the amendment as proposed would not change the allowance for large losses provision as described in paragraph (d)(5)(ii) of § 414.1420, so that when calculating the average marginal risk rate, we may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments under the payment arrangement greater than or equal to the total risk requirements. We also clarified that the proposal would not change the exception for small losses described in paragraph (d)(5)(iii).

We received comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal, and no commenters opposed our proposal. Two of these commenters stated that the proposal would provide greater flexibility in the design of other payer payment arrangements, and therefore, would encourage other payers to seek Other Payer Advanced APM determinations for their payment arrangements.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal, without modification, to amend § 414.1420(d)(5)(i) to provide that in event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures will be used for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of this section, while retaining the current exceptions for large losses and small losses as described in paragraphs (d)(5)(ii) and (d)(5)(iii) of this section.

(iii) Expected Expenditures

In the CY 2017 Quality Payment Program final rule (81 FR 77551), we established the definition of ''expected expenditures'' at § 414.1420(d)(6) to mean the Other Payer APM benchmark, except for episode payment models, for which it is defined as the episode target price. We also finalized at § 414.1420(d)(3)(ii) that, except for arrangements assessed under the Medicaid Medical Home Model financial risk and nominal amount standards, in order to meet the Other Payer Advanced APM nominal amount standard, a payment arrangement's level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures and the total potential risk must be at least 4 percent (81 FR 77471).

In the CY 2017 Quality Payment Program proposed rule (81 FR 28332), we proposed to measure three dimensions of risk under our generally applicable nominal amount standards: (1) Marginal risk, which refers to the percentage of the amount by which actual expenditures exceed expected expenditures for which an APM Entity would be liable under the APM; (2) minimum loss rate (MLR), which is a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk; and (3) total potential risk, which refers to the maximum potential payment for which an APM Entity could be liable under the APM. However, based on commenters' concerns regarding technical complexity, we finalized only the marginal risk and MLR requirements.

In the CY 2017 Quality Payment Program proposed rule (81 FR 28333), we explained that, to determine whether an APM satisfies the marginal risk portion of the nominal risk standard, we would examine the payment required under the APM as a percentage of the amount by which actual expenditures exceeded expected expenditures. We proposed to require that this percentage exceed a required marginal risk percentage of 30 percent regardless of the amount by which actual expenditures exceeded expected expenditures.

Our rationale for proposing the marginal risk requirement was that the inclusion of a marginal risk requirement would be intended to focus on maintaining a more than nominal level of likely risk under an Advanced APM

or an Other Payer Advanced APM. However, even with a marginal risk requirement, as there is under the Other Payer Advanced APM criteria, in the CY 2020 PFS proposed rule (84 FR 40837), we explained that we believe there is a need to amend the definition of expected expenditures to ensure there are more than nominal levels of average or likely risk under Other Payer Advanced APMs that meet the generally applicable benchmark-based nominal amount standard. Even with the current marginal risk requirement, we believe a more rigorous definition of expected expenditures is needed to avoid situations where the level of expected expenditures would be set in a manner that reduces the losses a participant might incur. For the same general reasons, we made a similar proposal to revise our definition of expected expenditures under the Advanced APM criteria in the CY 2020 PFS proposed rule (84 FR 40825). We also believe it is important that our definition of expected expenditures is consistent across both the Advanced APM and Other Payer Advanced APM criteria. We generally try to align the Advanced APM and Other Payer Advanced APM criteria to the extent feasible and appropriate.

We made this parallel proposal for the Other Payer Advanced APM criteria to similarly account for scenarios where a payment arrangement can have a sufficient total risk potential to meet our standard, and a sharing rate that results in adequate marginal risk if actual expenditures exceed expected expenditures, but where the level of expected expenditures reflected in the payment arrangement's benchmark or episode target price could be set in a way that substantially reduces the amount of loss a participant in the payment arrangement would reasonably expect to incur.

For a payment arrangement to meet the generally applicable benchmark-based nominal amount standard, we believe there should be not only the potential for financial losses based on expenditures in excess of the benchmark as provided in § 414.1420(d)(6), but also some meaningful likelihood that a participant might exceed the benchmark. If the benchmark is set in such a way that it is extremely unlikely that participants will exceed it, then there is little potential for participants to incur financial losses, and the amount of risk is essentially illusory.

Therefore, we proposed to amend the definition of expected expenditures in § 414.1420(d)(6). Specifically, we would continue to define expected expenditures, for the purposes of this section, as the Other Payer APM benchmark. For episode payment arrangements, expected expenditures would continue to mean the episode target price. However, for purposes of assessing financial risk for Other Payer Advanced APM determinations, the expected expenditures under the payment arrangement should not exceed the expenditures for a participant in the absence of the payment arrangement. The amended regulation would specify that if expected expenditures (that is, benchmarks) under the payment arrangement exceed the expenditures that the participant will be expected to incur in the absence of the payment arrangement, such excess expenditures are not considered when CMS assesses financial risk under the payment arrangement for Other Payer Advanced APM determinations.

We believe that this change would prevent the expected expenditures under the other payer payment arrangement being set in a manner that substantially reduces the amount of losses a participant may face while otherwise satisfying this Other Payer Advanced APM criterion.

We clarify that, in general, expected expenditures are expressed as a dollar amount, and may be derived from national, regional, APM Entity-specific, and/or practice-specific historical expenditures during a baseline period, or other comparable expenditures. However, we recognize expected expenditures under a payment arrangement are often risk-adjusted and trended forward, and may be adjusted to account for expenditure changes that are expected to occur as a result of participation in the payment arrangement. For the purpose of this definition of expected expenditures, we will not consider risk adjustments to be excess expenditures when comparing to the costs that an APM Entity will be expected to incur in the absence of the payment arrangement.

We believe that this amendment would allow us to ensure that there are more-than-nominal amounts of average or likely risk under an other payer payment arrangement that meets the generally applicable benchmark-based nominal amount standard. We believe that the amended definition of expected expenditures, particularly by our not considering excess expenditures, will provide a more definite basis for us to assess whether an APM Entity will bear more than a nominal amount of financial risk for participants under the generally applicable benchmark-based nominal amount standard.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed this proposal. A few of these commenters asserted that the proposal would add significant administrative burden to other payers because other payers would have to carry out significant analytical work to demonstrate compliance with the requirement. A few of these commenters also stated this additional effort would discourage other payers from developing other payer payment arrangements that may be Other Payer Advanced APMs. In addition, a few of these commenters stated that the proposal does not clearly state how CMS would either calculate or assess whether expected expenditures under the other payer payment arrangement exceed the expenditures that the participant will be expected to incur, or whether the other payer would be required to assess whether expected expenditures under the other payer payment arrangement exceed the expenditures that the participant will be expected to incur. One commenter stated the language in the proposal is confusing and does not explain how the expenditures that would be expected to occur in the absence of the arrangement will be calculated. Another commenter noted that the proposal does not provide enough detail on how the assessment would be conducted and stated the requirement would require ''difference-in-difference'' evaluations, which require robust evaluations of claims data. Furthermore, some commenters stated that the proposed change would result in fewer payment arrangements qualifying as Other Payer Advanced APMs.

Response: In proposing this amendment, we did not intend to place an administrative burden on payers and do not expect payers to undertake an additional analysis of claims data to demonstrate compliance. As part of our Other Payer Advanced APM monitoring and program integrity activities, we would expect payers submitting payment arrangements for Other Payer Advanced APM determinations to understand that they may be subject to random or targeted monitoring as part of participation in Quality Payment Program in the form of a request for a simple analysis provided by the payer demonstrating that the expected expenditures under the payment arrangement should not exceed the expenditures for a participants in the absence of the payment arrangement. At the time of submissions of other

payment arrangements from either payers or eligible clinicians, no additional analysis would be required. In addition, we are not requiring that any payer conduct any ''difference-in-difference'' evaluation to comply with this amendment. We are notifying other payers that they should take this requirement into account when they design new payment arrangements that they intend to satisfy the financial risk criterion by way of the benchmark-based nominal amount standard.

We acknowledge that there may be instances where, even if no additional analysis is required, this policy may lead to a payer not to make a submission of their payment arrangement for Other Payer Advanced APM determinations. However, we believe that this policy monitoring is important to the integrity of the program, and that any such impact on submissions will be minimal.

After considering public comments, we are finalizing our proposal to amend the definition of expected expenditures at § 414.1420(d)(6) without modification. We clarify that demonstrating compliance with this requirement should require only a minimal amount of analysis, if any, on the part of the payer or clinicians.

(iv) Excluded Items and Services Under Full Capitation Arrangements

In the CY 2017 Quality Payment Program final rule (81 FR 77551), we finalized a capitation standard at § 414.1420(d)(7) which provides that a capitation arrangement meets the Other Payer Advanced APM financial risk criterion. For purposes of § 414.1420(d)(3), we defined a capitation arrangement as a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the APM Entity. We clarified that arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program are not considered capitation arrangements for purposes of § 414.1420(d)(7).

In the CY 2019 PFS final rule (83 FR 59939), we made technical corrections to the Advanced APM financial risk capitation standard at § 414.1420(d)(7). These corrections clarified that our financial risk capitation standard applies only to full capitation arrangements where a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement or reconciliation is performed.

As we have begun to collect information on other payer payment arrangements for purposes of making Other Payer Advanced APM determinations, we have noticed that some payment arrangements that are submitted for CMS to determine as capitation arrangements consistent with § 414.1420(d)(7) include a list of services that have been excluded from the capitation rate, such as hospice care, organ transplants, or out-of-network emergency room services. In reviewing these exclusion lists, we believe that it may be appropriate for capitation arrangements to be considered ''full'' capitation arrangements even if they categorically exclude certain services from payment through the capitation rate. Therefore, in the CY 2020 PFS proposed rule (84 FR 40826), we solicited comment on how other payers define or determine what, if any, exclusions are reasonable in a given capitation arrangement. Specifically, we solicited comment on whether there are common industry practices to exclude certain categories of items and services from capitated payment rates and, if so, whether there are common principles or reasons for excluding those categories of services. In addition, we solicited comment on why such items or services are excluded.

We also solicited comment on how non-Medicare payers define or prescribe certain categories of services that are excluded with regard to global capitation payment arrangements. We also solicited comment on whether we should consider a capitation arrangement to be a full capitation arrangement even though it excludes certain categories of services from the capitation rate.

We received public comments responding to our solicitation for information. We appreciate the comments submitted and will take them into consideration for any potential future rulemaking on this issue. The comments that we received in response to this solicitation for information were applicable to both Advanced APMs and Other Payer Advanced APMs. For our responses to these comments, please see section III.K.4.c. of this final rule.

(4) Summary

In this section, we are finalizing the following policies:

- *Aligned Other Payer Medical Home Model:* We are finalizing our proposal to define the term Aligned Other Payer Medical Home Model as proposed. In addition, we are finalizing without modification our proposals that the CEHRT criterion and the use of quality measures criterion will apply to any Aligned Other Payer Medical Home Model for which we will make an Other Payer Advanced APM determination. We are also finalizing our proposal without modification to conform the financial risk and nominal amount standards for Aligned Other Payer Medical Home Models to the existing standards for Medicaid Medical Home Model financial risk and nominal amount standards, including the 50 eligible clinician limit.
- *Marginal Risk:* We are finalizing without modification our proposal that when the marginal risk rate in a payment arrangement varies depending on the amount by which actual/expenditures exceed expected expenditures, we will use the average marginal risk rate across all possible levels of actual expenditures for comparison to the marginal risk rate requirement, with exceptions for large losses and small losses as provided in § 414.1420(d)(5) without modification.
- *Expected Expenditures:* We are finalizing our proposal without modification to amend the definition of expected expenditures at § 414.1420(d)(6) to provide that, for assessing financial risk for Other Payer Advanced APM determinations for episode payment arrangements, the expected expenditures (episode target price) under the payment arrangement should not exceed the expenditures for a participant in the absence of the payment arrangement.

5. Quality Payment Program Technical Revisions

In the CY 2020 PFS proposed rule (84 FR 40837), we proposed certain technical revisions to our regulations to correct several technical errors and to reconcile the text of several of our regulations with the final policies we adopted through notice and comment rulemaking.

We proposed a technical revision to § 414.1405(f) of our regulations to specify that the exception for the application of the MIPS payment adjustment factors to model-specific payments is applicable starting in the 2019 MIPS payment year, not just for the 2019 MIPS payment year. This revision would align the regulation text with our final policy as stated in the preamble of the CY 2019 PFS final rule with comment period (83 FR 59887 through 59888) which makes clear that the exception begins with the 2019

MIPS payment year and continues in subsequent years.

We also proposed technical revisions to Table 59 of the CY 2019 PFS final rule with comment period (83 FR 59935) to correct two dates. Specifically we proposed to change the date for Medicare Health Plans: Guidance made available to ECs, then Submission Period Opens; it is currently listed as September 2020, and we proposed to change that date to August 2020. Similarly, we proposed to change the date for Remaining Other Payers: Guidance made available to ECs, then Submission Period Opens; it is currently listed as September 2020, and we proposed to change that to August 2020. These changes align with what was originally finalized in the CY 2018 Quality Payment Program final rule with comment period (82 FR 53864) which stated that the dates were to be August 2020, and which we did not propose or intend to change in the CY 2019 PFS final rule. Table 66 is included as the corrected Table 59 from the CY 2019 PFS final rule.

TABLE 66: Proposed Other Payer Advanced APM Determination Process for Medicaid, Medicare Health Plans, and Remaining Other Payers for QP Performance Period 2020 (Corrected "Table 59" from the CY 2020 PFS proposed rule)

	Payer Initiated Process	Date	Eligible Clinician (EC) Initiated Process*	Date
Medicaid	Guidance sent to states, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	September 2019
	Submission Period Closes	April 2019	Submission Period Closes	November 2019
	CMS contacts states and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and states and posts Other Payer Advanced APM List	December 2019
Medicare Health Plans	Guidance made available to Medicare Health Plans, then Submission Period Opens	April 2019	Guidance made available to ECs, then Submission Period Opens	August 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Medicare Health Plans and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Medicare Health Plans and posts Other Payer Advanced APM List	December 2020
Remaining Other Payers	Guidance made available to Remaining Other Payers, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	August 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Remaining Other Payers and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Remaining Other Payers and posts Other Payer Advanced APM List	December 2020

*Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

We also proposed technical revisions to §§ 414.1415(c)(6) and 414.1420(d)(7) to correct the internal citation. The current citation, 42 U.S.C. 422, is incorrect. It should instead be 42 CFR part 422. We also proposed technical revisions to § 414.1420(d)(5). We clarify that ''APM'' in § 414.1420(d)(5) should be ''other payer payment arrangement.'' In the CY 2019 PFS final rule, we finalized deleting § 414.1420(d)(3)(ii)(B) and consolidating § 414.1420(d)(3)(ii)(A) into § 414.1420(d)(3)(ii), but that change was not applied to the regulation. We proposed to revise the regulation accordingly. Relatedly, we proposed to amend § 414.1420(d)(5)(i), (ii), and (iii) to state in ''paragraph (d)(3)(ii)'' of this section instead of ''paragraph (d)(3)(ii)(A)'' of this section. We also proposed to clarify that ''Other Payer Advanced APM'' in § 414.1420(d)(5)(ii) should be ''other payer payment arrangement,'' as the marginal risk rate requirements are applied to any other payer payment arrangement that CMS assesses against the Other Payer Advanced APM criteria. These revisions are technical in nature and do not change any substantive policies for the Quality Payment Program.

We did not receive any comments on these proposed technical revisions.

We are finalizing these technical revisions as proposed.

IV. Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes

A. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

B. Annual Update to the Code List

1. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h)).

The definition of DHS at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not DHS and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

ESRD-related oral-only drugs, which are drugs or biologicals with no injectable equivalents or other forms of administration other than an oral form, were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. On December 19, 2014, section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these oral-only drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and thus, are DHS.

The Code List was last updated in Tables 28 and 29 of the CY 2019 PFS final rule (83 FR 59718).

2. Response to Comments

We received no comments relating to the Code List that became effective January 1, 2019.

3. Revisions Effective for CY 2020

The updated, comprehensive Code List effective January 1, 2020, is available on our website at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.*

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status.

Tables 67 and 68 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2020. Tables 67 and 68 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

TABLE 67: Additions to the Physician Self-Referral List of CPT[1]/HCPCS Codes

CLINICAL LABORATORY SERVICES
{No additions}
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
90912 Bfb training 1st 15 min
90913 Bfb training ea addl 15 min
97129 Ther ivntj 1st 15 min
97130 Ther ivntj ea addl 15 min
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
0558T Ct scan f/biomchn ct alys
74221 X-ray xm esophagus 2cntrst
74248 X-ray sm int f-thru std
74251 X-ray xm sm int 2cntrst std
74270 X-ray xm colon 1cntrst std
74280 X-ray xm colon 2cntrst std
78429 Myocrd img pet 1 std w/ct
78430 Myocrd img pet rst/strs w/ct
78431 Myocrd img pet rst & strs ct
78432 Myocrd img pet 2rtracer
78433 Myocrd img pet 2rtracer ct
78434 Aqmbf pet rest & rx stress
93356 Myocrd strain img spckl trck
RADIATION THERAPY SERVICES AND SUPPLIES
A9590 Iodine i-131 iobenguane 1mci
64625 Rf abltj nrv nrvtg si jt
78830 Rp loclzj tum spect w/ct 1
78831 Rp loclzj tum spect 2 areas
78832 Rp loclzj tum spect w/ct 2
78835 Rp quan meas single area
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
90694 Vacc acc aIIV4 no prsrv 0.5ml im

[1]CPT codes and descriptions only are copyright 2019 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 68: Deletions from the Physician Self-Referral List of CPT[1]/HCPCS Codes

CLINICAL LABORATORY SERVICES
0357T Cryopreservation oocyte(s)
0020U Rx test prsmv ur w/def conf
0028U Cyp2d6 gene cpy nmr cmn vrnt
0057U Onc sld org neo mrna 51 gene
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
90911 Biofeedback peri/uro/rectal
95831 Limb muscle testing manual
95832 Hand muscle testing manual
95833 Body muscle testing manual
95834 Body muscle testing manual
G0460 Autologous PRP for ulcers
G0515 Cognitive skills development
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
74241 X-ray exam upper gi tract
74245 X-ray exam upper gi tract
74247 Contrst x-ray uppr gi tract
74249 Contrst x-ray uppr gi tract
78205 Liver imaging (3D)
78206 Liver image (3d) with flow
78320 Bone imaging (3D)
78607 Brain imaging (3D)
78647 Cerebrospinal fluid scan
78710 Kidney imaging (3D)
78805 Abscess imaging ltd area
78806 Abscess imaging whole body
78807 Nuclear localization/abscess
93965 Extremity study
RADIATION THERAPY SERVICES AND SUPPLIES
{No deletions}
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
{No deletions}

[1]CPT codes and descriptions only are copyright 2019 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

V. Interim Final Rule With Comment Period [CMS–1715–IFC]

A. Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS Codes G2082 and G2083)

On March 5, 2009, the U.S. Food and Drug Administration (FDA) approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)).[120] Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety

[120] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.*

concerns to help ensure the benefit of the medication outweigh its risks.[121]

Patients with major depression disorder who, despite trying at least two antidepressant treatments given at adequate doses for an adequate duration in the current episode, have not responded to treatment are considered to have TRD.[122] TRD is especially relevant for Medicare beneficiaries. Depression in the elderly is associated with suicide more than at any other age; adults 65 or older constitute 16 percent of all suicide deaths. The decrease in average life expectancy for those with depressive illness, including Medicare beneficiaries, is 7 to 11 years. Depression is a major predictor of the onset of stroke, diabetes, and heart disease; it raises patients' risk of developing coronary heart disease and the risk of dying from a heart attack nearly threefold.[123] There has also been a longstanding need for additional effective treatment for TRD, a serious and life-threatening condition.[124]

A treatment session of esketamine consists of instructed nasal self-administration by the patient, followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use.[125] Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56mg dose) or three (3) devices (for an 84 mg dose) per treatment.

After reviewing the Spravato Prescribing Information, Medication Guide, and REMS requirements, we have concluded that effective and appropriate treatment of TRD with esketamine requires discrete services of a medical professional, meaning those that may furnish and report E/M services under the PFS, both during an overall course of treatment and at the time the drug is administered.[126] Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product: The product is only available through a restricted distribution system under a REMS; [127] patients must be monitored by a health care provider for at least 2 hours after receiving their Spravato dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product will only be administered in a certified medical office where the health care provider can monitor the patient.[128] Further information regarding certification of medical offices is available at *www.SPRAVATOrems.com* or 1–855–382–6022.

Because this newly available treatment regimen addresses a particular and urgent need for people with TRD, including Medicare beneficiaries, we recognize that it is in the public interest to ensure appropriate patients have access to this potentially life-saving treatment. We recognize, however, that the services and resources involved in furnishing this treatment are not adequately reflected in existing coding and payment under the PFS, or otherwise under Medicare Part B. Given the FDA approval conditions/requirements including that the drug is only available as an integral component of a physicians' service, the absence of existing HCPCS coding that would adequately describe the service with the provision of the product, and our understanding based on review of the Spravato Prescribing Information, Medication Guide, and REMS requirements, we do not believe the Medicare beneficiaries in the greatest medical need of this treatment would be likely to have access to it until such time that Medicare coding and payment are updated. Medicare coding and payment policies are generally adopted through annual updates to the PFS. Unless we adopt coding and payment changes for this treatment beginning January 1, 2020, we believe that the next practicable alternative would be either standalone rulemaking or PFS rulemaking for 2021. Both of these alternatives would risk the lives of Medicare beneficiaries with TRD for several months to over a year.

Therefore, to facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we are creating two new HCPCS G codes, G2082 and G2083, effective January 1, 2020 on an interim final basis. For CY 2020, we are establishing RVUs for these services that reflect the relative resource costs associated with the evaluation and management (E/M), observation and provision of the self-administered esketamine product using HCPCS G codes. We note that we have historically established coding and payment on an interim final basis for truly new services when it is in the public interest to do so. Like most other truly new services, we expect diffusion of this kind of treatment into the market will take place over several years, even though we expect some people to benefit immediately. Consequently, the expected impact on other PFS services is negligible for 2020, and we will consider the public comments we receive on this interim final policy as we consider finalizing coding or payment rules for this treatment beginning in 2021. The HCPCS G-codes are described as follows:

- HCPCS code G2082: *Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.*
- HCPCS code G2083: *Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation.*

In developing the interim final values for these codes, we used a building block methodology that sums the values associated with several codes. For the overall E/M and observation elements of the services, we are incorporating the work RVUs, work time and direct PE inputs associated with a level two office/outpatient visit for an established patient, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other*

[121] *https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems.*

[122] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.*

[123] *https://www.cms.gov/medicare-coverage-database/details/technology-assessments-details.aspx?TAId=105&bc=AAAQAAAAAAAA&.*

[124] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.*

[125] Ibid.

[126] *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211243.*

[127] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.*

[128] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.*

physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family), which has a work RVU of 0.48 and a total work time of 16 minutes, which is based on a pre-service evaluation time of 2 minutes, an intraservice time of 10 minutes, and a postservice time of 4 minutes. We are also incorporating CPT codes 99415 (*Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (List separately in addition to code for outpatient Evaluation and Management service))* and 99416 (*Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; each additional 30 minutes (List separately in addition to code for prolonged service))* in which neither code has a work RVU, but includes direct PE inputs reflecting the prolonged time for clinical staff under the direct supervision of the billing practitioner.

Additionally, to account for the cost of the provision of the self-administered esketamine as a direct PE input, we are incorporating the wholesale acquisition cost (WAC) data from the most recent available quarter. For HCPCS code G2082, we are using a price of $590.02 for the supply input that describes 56 mg (supply code SH109) and for HCPCS code G2083, we are using a price of $885.02 for the supply input describing 84 mg of esketamine (supply code SH110).

We note that we are valuing these two HCPCS codes, in part, on the basis of a level 2 established patient office/outpatient E/M visit; consequently, for purposes of relevant Medicare conditions of payment, reporting these codes is similar to reporting a level 2 office/outpatient E/M visit code. In addition to seeking comment on the interim final values we are establishing for HCPCS codes G2082 and G2083, we also seek comment on the assigned work RVUs, work times, and direct PE inputs.

Under circumstances where the health care professional supervising the self-administration and observation does not also provide the esketamine product, the provider cannot report HCPCS codes G2082 or G2083. Rather, the visit and the extended observation (by either the billing professional or clinical staff) could be reported using the existing E/M codes that describe the visit and the prolonged service of the professional or the clinical staff. CMS will monitor claims data to safeguard against duplicative billing for these services and items.

Historically, supply input prices are updated on a code by code basis and periodically through annual notice and comment rulemaking. The prices, including for a variety of pharmaceutical products, are not routinely updated like Part B drugs paid under the ASP methodologies. For the supply inputs for the esketamine product, used in developing rates for HCPCS codes G2082 and G2083, we are using the most recent available quarter of WAC data for 2020 pricing, but we anticipate using either data that is reported for determining payments under section 1847A of the Act (such as ASP) or compendia pricing information (such as WAC) in future years and expect to address this issue in further rulemaking. We seek comments on how to best establish input prices for the esketamine product, as well as other potential self-administered drugs that necessitate concurrent medical services, under PFS ratesetting in future years.

We note that there is a 60-day public comment period following publication of this interim final rule for the public to comment on these interim final amendments to our regulations. We refer readers to the **ADDRESSES** section of the final rule for instructions on submitting public comments. Comments are due by the ''Comment date'' specified in the **DATES** section of this rule.

B. Waiver of Proposed Rulemaking for Provisions

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. Section 553(b)(B) of the APA provides for exceptions from the notice and comment requirements; in cases in which these exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) due to the urgent need of some Medicare beneficiaries for effective treatment for TRD, a serious and life-threatening condition. The U.S. Food and Drug Administration (FDA) approved Spravato (esketamine) nasal spray on March 5, 2019, used in conjunction with an oral antidepressant, for treatment of adults who have tried other antidepressant medications but have not benefited from them. Because of the treatment's unique method of delivery, specifically the necessary inclusion of a self-administered drug product as part of a uniquely identifiable service of a medical professional (as required through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS),[129] existing Medicare coding and payment policies would not permit appropriate payment for these services. Consequently, Medicare beneficiaries' access to this treatment would be impeded without Medicare coding and payment policy changes established in this final rule with comment period. Given the longstanding need for additional effective treatments for patients with TRD and the potential risk to the lives of the Medicare beneficiaries with TRD, we believe it is in the public interest to adopt these interim final policies to ensure access by making available appropriate payment to physicians and other practitioners for provision of this service as soon as practicable, and that the lack of an appropriate payment mechanism would jeopardize or significantly delay access to this treatment regimen. We find that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing these payment policies on an interim basis. We also find that delaying implementation of these policies is unnecessary because the impact on other PFS services for 2020 is negligible and the practical alternative for this treatment is no payment under Medicare Part B. In either case, payments for 2021 and beyond would be informed by public comments.

Therefore, we find good cause to waive the notice of proposed rulemaking as provided under section

[129] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.*

1871(b)(2)(C) of the Act and section 533(b)(B) of the APA and to issue this interim final rule with an opportunity for public comment. We are providing a 60-day public comment period as specified in the **DATES** section of this document.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35), we are required to publish a 30-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

Our August 14, 2019 (84 FR 40482) proposed rule solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements. We received PRA-related comments pertaining to the Open Payments Program and Quality Payment Program. A summary of the comments and our response are set out below, under sections V.B.5. and V.B.7.c.(3)(b).

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 69 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 69: National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43-3021	19.00	19.00	38.00
Bookkeeping, Accounting, and Auditing Clerks	43-3031	22.46	22.46	44.92
Chief Executive	11-1011	96.22	96.22	192.44
Compliance Officer	13-1041	41.85	41.85	83.70
Computer Systems Analysts	15-1121	45.01	45.01	90.02
Health Diagnosing and Treating Practitioners	29-1000	49.02	49.02	98.04
Licensed Practical Nurse (LPN)	29-2061	22.62	22.62	45.24
Medical Secretary	43-6013	17.83	17.83	35.66
Physicians	29-1060	101.43	101.43	202.86
Practice Administrator (Medical and Health Services Managers)	11-9111	54.68	54.68	109.36

As indicated, we adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs) (§§ 414.800 through 414.806)

As described in section II.G. of this final rule, section 2005 of the SUPPORT for Patients and Communities Act establishes a new Medicare Part B benefit for OUD treatment services furnished by OTPs for episodes of care beginning on or after January 1, 2020. In this final rule we are adopting our proposals to use the payment methodology in section 1847A of the Act, which is based on Average Sales Price (ASP), to set the payment rates for the ''incident to'' drugs and ASP-based payment to set the payment rates for the oral product categories, when we receive manufacturers' voluntarily-submitted ASP data for these drugs.

The burden consists of the time/cost for manufacturers of oral opioid agonist or antagonist treatment medications (that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for use in the treatment of OUD) to voluntarily prepare and submit their ASP data to CMS.

The burden for such reporting is currently approved by OMB under control number 0938–0921 (CMS–10110) and will remain unchanged (13 hours per response, 4 responses per year, 180 respondents, and 9,360 total hours) since our currently approved burden already accounts for the voluntary reporting of ASP data. We estimate that there are approximately 15 manufacturers of oral drugs used for treatment of opioid use disorder (OUD). We believe that approximately 10 of the 15 manufacturers already report ASP data to CMS for other drugs, and thus up to 5 manufacturers may newly report ASP data to CMS. However, we note that some of these new respondents may have subsidiary or similar relationships with manufacturers that already report ASP data and may be able to submit their data with a current respondent. While the policies we are adopting in

this CY 2020 PFS final rule may slightly increase the number of respondents, our 180 respondent estimate historically fluctuates over time as new Part B drug manufacturers are added while others leave or consolidate. The annual fluctuation in respondents in the past has typically been +/- 5 to 10 manufacturers per year; over the past few years, the annual fluctuation has sometimes been greater, ranging from −13 to +11, but over that same period the overall average of the annual fluctuation is near zero. As a result, the potential slight increase in respondents associated with voluntary reporting for oral drugs used in the treatment of OUD, remains unchanged from the currently approved burden estimate of 180 respondents. In addition, we believe that additional voluntary reporting for oral drugs used for treatment of OUD by those manufacturers that currently report ASP data to CMS for other drugs will impose minimal additional burden. Consequently, we are not making any changes under the aforementioned control number. However, we will continue to monitor the number of respondents to account for various factors such as a change in the number of voluntary submissions from oral OUD drug manufacturers, as well as other issues that may not be related to the voluntary reporting for oral drugs used in OTPs, such as manufacturer consolidations, and new Part B drug and biological manufacturers. We will revise the burden estimate as needed.

We received no comments in relation to our proposed burden estimates.

2. ICRs Regarding the Ground Ambulance Data Collection System

Section 1834(l)(17)(A) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, we did not set out in the proposed rule the burden of the collection of information under the data collection system, and we are similarly not setting out that burden in this final rule. Please refer to section VII.F.2. of this final rule for a discussion of the impacts associated with the ground ambulance data collection system.

3. ICRs Regarding Intensive Cardiac Rehabilitation (§ 410.49)

Section 410.49(b)(1)(vii) and (viii) of this final rule will expand the covered conditions to chronic heart failure and add other cardiac conditions as specified through the national coverage determination (NCD) process. We do not anticipate the need to use the NCD process to add additional covered conditions in the near future. In the unlikely event an NCD request is submitted, it will be covered by OMB control number 0938–0776 (CMS–R–290), which will not expire until February 29, 2020. We are not making any changes under that control number since this rule does not impose changes to the currently approved submission process or burden.

We did not receive public comments on the ICRs for intensive cardiac rehabilitation.

4. ICRs Regarding the Medicare Shared Savings Program (42 CFR part 425)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden under the authority of the PRA. Please refer to section VII.F.6. of this final rule for a discussion of the impacts associated with the changes to the Shared Savings Program quality reporting requirements included in this final rule.

5. ICRs Regarding the Open Payments Program

Section III.F. of this rule: (1) Expands the definition of ''covered recipient,'' (2) modifies ''nature of payment'' categories, and (3) standardizes data on reported covered drugs, devices, biologicals, or medical supplies.

Expanding the Definition of ''Covered Recipient'' (§§ 403.902, 403.904, and 403.908): This rule expands the definition of a ''covered recipient'' in accordance with the SUPPORT Act to include physician assistants, nurse practitioners, clinical nurse specialists, nurse anesthetists, and certified nurse midwifes. The definition currently includes certain physicians and teaching hospitals. Section 6111(c) of the SUPPORT Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the changes to the definition of a covered recipient included in the SUPPORT Act. In this regard we are not setting out burden under the authority of the PRA. Such estimates can be found in the RIA under section VII.F.7. of this final rule.

Modification of the ''Nature of Payment'' Categories (§§ 403.902 and 403.904): The following changes will be submitted to OMB for approval under control number 0938–1237 (CMS–10495). Subject to renewal, the control number is currently set to expire on March 31, 2021. It was last approved on March 21, 2018, and remains active.

The changes will modify the ''nature of payment'' categories and provide more options for applicable manufacturers and GPOs to capture the nature of the payment made to the covered recipient. To accommodate this change, we project that reporting entities will need to update their system to incorporate the additional categories. We estimate, based on the trends in the number of entities that report every year, that there are 1,600 reporting entities and estimate, using the number of records that these entities report as a proxy for size of the entity. The total number of entities that report fluctuates year to year but has been close to 1,600 for the last two program years. We also estimate that 38 percent (or 611 entities) are small, 29 percent (or 457 entities) are medium, and 33 percent (or 532 entities) are large. We also estimate that 25 percent of reporting entities (400) will need to make minor, one-time updates to their data collection processes because they expect to report a transaction with one of the new categories. Among the 400 entities, we estimate it will take between 5 and 30 hours per entity depending on the size of the entity (with large companies requiring more time) at $44.92/hr for support staff. For all of these entities, we estimate a subtotal of 5,895 hours [(30 hr for a large entity × 133 entities) + (10 hr for a medium entity × 114 entities) + (5 hr for a small entity × 153 entities)] at a cost of $264,804 (5,895 hr × $44.92/hr).

We also expect that all entities will need to make minor, one-time adjustments to their submission processes. For each entity we estimate that this will take 2 to 5 hours at $44.92/hr (with larger entities requiring more time) for support staff and 1 hour at $83.70/hr for compliance officers. For all entities, we estimate a subtotal of 7,767 hours [(5 hr for support staff at a large entity × 532 entities) + (5 hr for support staff at a medium entity × 457 entities) + (2 hr for support staff at a small entity × 611 entities) + (1 hr for compliance officer at each entity regardless of size × 1,600 entities)] at a cost of $410,941 [(2,660 hr for support staff at large entities × $44.92/hr) + (2,285 hr for support staff at medium entities × $44.92/hr) + (1,222 hr for support staff at small entities × $44.92/

hr) + (1,600 hr for compliance officers across all entities × $83.70/hr)].

In aggregate, we estimate a one-time burden of 13,662 hours (5,895 hr + 7,767 hr) at a cost of $675,745 ($264,804 + $410,941) to implement. After these adjustments are made, we do not anticipate any ongoing added burden beyond what is currently approved under the aforementioned control number. We are maintaining these burden estimates as we believe they are representative of the array of potential burden associated with these changes.

TABLE 70—BURDEN TO MODIFY NATURE OF PAYMENT CATEGORIES

Description	Hours	Cost
Burden to update collection processes for entities that expect to report a transaction with a new Nature of Payment category	5,895	$264,804
Burden to update submission processes and systems to account for the new Nature of Payment categories	7,767	410,941
Total	13,662	$675,745

Standardizing Data Reporting for Covered Drugs, Devices, Biologicals, or Medical Supplies (§§ 403.902 and 403.904): The following changes will be submitted to OMB for approval under control number 0938–1237 (CMS–10495). Subject to renewal, the control number is currently set to expire on March 31, 2021. It was last approved on March 21, 2018, and remains active.

Applicable manufacturers and GPOs will need to accommodate the reporting of device identifiers. The following estimates may vary because the information collection system changes that are needed will vary since some entities may already be capturing this information in their systems while others may not.

We estimate, based on an analysis of currently available data, that approximately 850 entities (approximately 53 percent of an assumed 1,600) will need to report at least one record with a device identifier and that 450 of those entities do not already collect the device identifier. For this analysis we assumed that 38 percent (172 = 450 × 0.38) of the entities will be small, 29 percent (128 = 450 × 0.29) will be medium, and 33 percent (150 = 450 × 0.33) will be large. We differentiate because we assume that larger companies will incur more burden to make the changes needed to begin reporting device identifiers because they have more complex systems and potentially more records to report. The number of submitted records will not change, but this rule will add a new data element that may need to be reported along with some or all of an entity's records. The precise tasks will vary by entity, but may include developing processes for gathering device identifier information or systems for collecting the data.

For the 450 entities that will be required to start collecting device identifiers, we estimate that this task will take between 20 and 100 hours for support staff depending on the size of the company (with larger companies requiring more time) at $44.92/hr. For all entities, we estimate a subtotal of 24,840 hours [(100 hr for a large entity × 150 entities) + (50 hr for a medium entity × 128 entities) + (20 hr for a small entity × 172 entities)] at a cost of $1,115,813 [(15,000 hr for support staff at a large entity × $44.92/hr) + (6,400 hr for support staff at a medium entity × $44.92/hr) + (3,440 hr for support staff at a small entity × $44.92/hr)].

For the 850 entities that we expect will be required to begin reporting a device identifier, we estimate that this would take support staff between 10 and 40 hours per entity (with larger companies requiring more time) at $44.92/hr and 2 hours at $83.70/hr for compliance officers. For all entities, we estimate a subtotal of 21,100 hours [(40 hr for support staff at a large entity × 282 entities) + (20 hr for support staff at a medium entity × 244 entities) + (10 hr for support staff at a small entity × 324 entities) + (2 hr for compliance officers at every entity regardless of size × 850 entities)] at a cost of $1,013,740 [(11,280 hr for support staff at large entities × $44.92/hr) + (4,880 for support staff at medium entities × $44.92/hr) + (3,240 for support staff at small entities × $44.92/hr) + (1,700 hr for compliance officers across all entities regardless of size × $83.70/hr)].

We also assume that the remaining 750 entities not planning to submit a device identifier will have a small amount of burden associated with updating their submission processes. We estimate that this will take support staff between 2 and 10 hours per entity (with larger entities requiring more time) at $44.92/hr and 2 hours for compliance officers at $83.70/hr. For all entities, we estimate a subtotal of 5,637 hours [(10 hr for support staff at a large entity × 249 entities) + (5 hr for support staff at a medium entity × 215 entities) + (2 hr for support staff at a small entity × 286 entities) + (750 hr for compliance officers at all entities regardless of size × 2 hr)] at a cost of $311,384 [(2,490 hr for support staff at large entities × $44.92/hr) + (1,075 hr for support staff at medium entities × $44.92/hr) + (572 hr for support staff at small entities × $44.92/hr) + (1,500 hr for compliance officers at all entities regardless of size × $83.70/hr)].

In aggregate, we estimate a one-time burden of 51,577 hours (24,840 hr + 21,100 hr + 5,637 hr) at a cost of $2,440,937 ($1,115,813 + $1,013,740 + $311,384) to implement. After these adjustments are made, we do not anticipate there being any ongoing added burden beyond what is currently approved under the aforementioned control number. We are maintaining these burden estimates as we believe they are representative of the array of potential burden associated with these changes.

TABLE 71—BURDEN FOR CHANGES TO STANDARDIZE DATA ON REPORTED COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES

Description	Hours	Cost
First year data collection burden for entities that do not currently collect a device identifier	24,840	$1,115,813
First year submission burden for all entities that will be required to report a device identifier	21,100	1,013,740
One time submission process and system updates for entities not reporting a device identifier	5,637	311,384

TABLE 71—BURDEN FOR CHANGES TO STANDARDIZE DATA ON REPORTED COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES—Continued

Description	Hours	Cost
Total	51,577	$2,440,937

Comment: One commenter requested that CMS consider the potential additional burden on reporting entities based on the expanded definition of covered recipients.

Response: We recognize that there is an increased data reporting requirement associated with implementation of these statutory requirements, but the expanded definition is required by statute. The estimated burden of Open Payments program is outlined under OMB control number 0938–1237. Section VII.F.7.a. of this final rule provides an estimate of the anticipated regulatory impact, although section 6111(c) of the SUPPORT Act states that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the changes to the definition of a covered recipient. As implementation plans are made, we will work to provide guidance, technical assistance, and operational efficiencies to help reduce the potential burden as much as possible.

Comment: One commenter further stated that they believe the burden estimate to add DI information to the Open Payment dataset is greater than CMS assumed. The commenter would like to provide input to CMS on the implementation of this requirement.

Response: When making this burden estimate, we took into account all of the current reporting entities and the array of demographics. We divided the group into several smaller categories based on entity size and made assumptions about the effort needed to make system and process changes. We assume that our estimates for each category will be low for some entities, but high for others. As we work through implementing these changes, we hope stakeholders will continue to provide feedback during working sessions to ensure our data collection system is easy to use and provides clear information.

6. ICRs Regarding Medicare Enrollment of Opioid Treatment Programs

The following discusses the burden estimates we proposed regarding the enrollment of OTP programs.

As mentioned in section III.H. of this final rule, OTP providers will be required to enroll in Medicare via the paper or internet-based version of the Form CMS–855B (or its successor application) and any applicable supplement, pay the application fee, submit fingerprints, and complete a provider agreement.

Based on SAMHSA statistics and our internal data, we generally estimated that: (1) There are about 1,700 certified and accredited OTPs eligible for Medicare enrollment; and (2) 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year), bringing the total amount of OTPs eligible to enroll to approximately 1,900 over the next 3 years.

Form Completion (§ 424.67(b)): We estimated that it would take each OTP an average of 3 hours to obtain and furnish the information on the Form CMS–855B (OMB control number: 0938–0685) and a new supplement thereto designed to capture information unique to OTPs. Per our experience, we believe that the OTP's medical secretary would be responsible for securing and reporting data on the Form CMS–855B and new accompanying OTP supplement. We estimated that this task would take approximately 2.5 hours; of this amount, roughly 30 minutes would involve completion of the data on the supplement, though this timeframe could be higher or lower depending upon the number of individuals whom the OTP must list. Additionally, the form would be reviewed and signed by a health diagnosing and treating practitioner of the OTP, a process we estimated would take 30 minutes. We project a first-year burden of 5,301 hours (1,767 entities × 3 hr) at a cost of $244,146 (1,767 entities × ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)), a second-year burden of 201 hours (67 entities × 3 hr) at a cost of $9,257 (67 entities × ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)), and a third-year burden of 198 hours (66 entities × 3 hr) at a cost of $9,119 (66 entities × ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)). In aggregate, we estimated a burden of 5,700 hours (5,301 hr + 201 hr + 198 hr) at a cost of $262,522 ($244,146 + $9,257 + $9,119). When averaged over the typical 3-year OMB approval period, we estimate an annual burden of 1,900 hours (5,700 hr/3) at a cost of $87,507 ($262,522/3).

A copy of the draft OTP supplement was made available online, and we welcomed public comment on: (1) Its contents; (2) the usefulness of the data to be captured thereon; and (3) the anticipated burden of completion. We received no comment and are finalizing the supplement as well as our burden estimates as proposed.

Fingerprinting (§ 424.518): In this rule, OTPs will be subject to high categorical risk level screening under § 424.518, which requires the submission of a set of fingerprints for a national background check (via FBI Applicant Fingerprint Card FD–258) from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the OTP. Since the burden is currently approved by OMB as a common form (FD–258) under control number 1110–0046, we are not setting out such burden. However, an analysis of the impact of this requirement can be found in the RIA section of this rule.

Application Fee (§ 424.514): As already discussed in this rule, each OTP will be required to pay an application fee at the time of enrollment. The application fee does not meet the definition of a ''collection of information'' (5 CFR 1320.3(c)) and, as such, is not subject to the requirements of the PRA. Although we are not setting out such burden under this PRA section, the cost is scored under section VII.F.8. of the RIA.

Provider Agreement (§ 424.67(b)(7)): OTPs will also have to complete a provider agreement in order to enroll in Medicare. The burden for reporting and completing the Provider Agreement Form CMS–1561 and –1561A (OMB control number 0938–0832) was based on SAMHSA statistics. We estimate that there are about 1,700 already certified and accredited OTPs eligible for Medicare enrollment initially; approximately 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year). We anticipate that it would take the OPT 5 minutes at $192.44/hr for a Chief Executive to review and sign the CMS–1561 or CMS–1561A, and an additional 5 minutes at $35.66/hr for a Medical Secretary to file the document when fully executed.

In aggregate, we estimate a 3-year burden of 317 hours ([1,767 OPTs for year 1 + 67 OTPs for year 2 + 67 OTPs for year 3] × 10 min/60) at a cost of $36,154 ([317 hr/2 respondents ×

$192.44/hr] + [317 hr/2 respondents × $35.66/hr]). This results, roughly, in a Year 1 burden of 295 hours at a cost of $33,623, a Year 2 burden of 11 hours at a cost of $1,272, and a Year 3 burden of 11 hours at a cost of $1,254. Over the course of OMB's typical 3-year approval period, we estimate an average annual burden of 106 hours (317 hr/3 years) at a cost of $12,051 ($36,154/3 years).

Total: Table 72 summarizes our foregoing burden estimates.

TABLE 72: Combined Burden Related to Enrollment of OTPs (Completion of CMS-855B and CMS-1561/-1561A)

	Year 1	Year 2	Year 3	Total	Average Annual Burden
CMS-855B Time (Hours)	5,301	201	198	5,700	1,900
CMS-1561/-1561A Time (Hours)	295	11	11	317	106
TOTAL	**5,596**	**212**	**209**	**6,017**	**2,006**
CMS-855B Cost ($)	244,146	9,257	9,119	262,522	87,507
CMS-1561/-1561A Cost ($)	33,623	1,272	1,254	36,154	12,051
TOTAL	**277,769**	**10,529**	**10,373**	**298,676**	**99,558**

We received no comments on our proposed requirements and burden estimates and are therefore finalizing them without change. The requirement and burden estimates will be submitted to OMB for approval under control number 0938–0685 (Form CMS–855B; ''Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers'') and 0938–0832 (Form CMS–1561/-1561A; ''Health Insurance Benefit Agreement'').

7. The Quality Payment Program (42 CFR Part 414 and Section III.K. of This Final Rule)

a. Background

(1) ICRs Associated With MIPS and Advanced APMs

The Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs.

The ICRs reflect this final rule's policies, as well as policies in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), and the CY 2019 PFS final rule (83 FR 59452).

(2) Summary of Quality Payment Program Changes: MIPS

(a) Summary of Changes to our Currently Approved Burden Estimates

As discussed in more detail in section VI.B.7, the MIPS ICRs consist of: Registration for virtual groups; qualified registry self-nomination applications; and QCDR self-nomination applications; CAHPS survey vendor applications; Quality Payment Program Identity Management Application Process; quality performance category data submission by Medicare Part B claims collection type, QCDR and MIPS CQM collection type, eCQM collection type, and CMS web interface submission type; CAHPS for MIPS survey beneficiary participation; group registration for CMS web interface; group registration for CAHPS for MIPS survey; call for quality measures; reweighting applications for Promoting Interoperability and other performance categories; Promoting Interoperability performance category data submission; call for Promoting Interoperability measures; improvement activities performance category data submission; nomination of improvement activities; and opt-out of Physician Compare for voluntary participants.

Two MIPS ICRs show changes in burden due to finalized policies: QCDR self-nomination applications and Call for Quality Measures. For the QCDR self-nomination applications ICR, we have decreased our estimate of the number of QCDR measures QCDRs will submit for approval from 9 to 2 (-7 measures) due to the finalized proposal to require measure testing prior to submission for approval. We have also increased our estimate of the time required to submit a QCDR measure by 1.5 hours due to the requirement for QCDRs to link their QCDR measures as feasible to at least one cost measure, improvement activity, or MIPS Value Pathways starting with the 2021 self-nomination period (+1 hour); and the requirement for QCDR measure stewards to submit measure testing data as part of the self-nomination process for each QCDR measure (+0.5 hours). The net effect of these changes is a reduction in burden per QCDR to self-nominate from 12 hours to 8 hours (-4 hours). For the Call for Quality Measures, we have increased our estimate of the time required to nominate a quality measure for consideration by 1 hour due to the requirement that MIPS quality measure stewards link their MIPS quality measures to existing and related cost measures and improvement activities and provide rationale for the linkage.

The remaining changes to our currently approved burden estimates are adjustments to reflect better understanding of the impacts of policies finalized in previous rules, as well as the use of updated data sources available at the time of publication of this final rule.

We are not making any changes to the following ICRs: Registration for virtual groups, CAHPS survey vendor applications, Quality Payment Program Identity Management Application Process, CAHPS for MIPS survey beneficiary participation, and group registration for CAHPS for MIPS survey. See section VI.B.7.n. of this final rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted due to two primary reasons. First, we anticipate the number of QPs to increase because of total expected growth in Advanced APM participation as new models that are Advanced APMs for which we do not yet have enrollment data become available for participation. The additional QPs will be excluded from MIPS and likely not report. Second, it is difficult to predict what eligible clinicians who may report voluntarily

will do in the 2020 MIPS performance period compared to the 2018 MIPS performance period, and therefore, the actual number of participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data.

The revised requirements and burden estimates for all Quality Payment Program ICRs (except for CAHPS for MIPS and virtual groups election) will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). The CAHPS for MIPS Survey is approved under OMB control number 0938–1222 (CMS–10450). The Virtual Groups Election is approved under OMB control number 0938–1343 (CMS–10652).

(b) Summary of Changes to Burden Estimates Provided in the CY 2020 PFS Proposed Rule

In the CY 2020 PFS proposed rule (84 FR 40838 through 40881), we used respondent data from the 2017 MIPS performance period for the quality, Promoting Interoperability, and improvement activities performance categories with the sole exception of 104 CMS Web Interface respondents, which was based on the number of groups who submitted data for the quality performance category via the CMS Web Interface for the 2018 MIPS performance period. For this final rule, we have updated our respondent estimates for each of these performance categories with data from the 2018 MIPS performance period.

Our participation estimates are reflected in Tables 78, 79 and 80 for the quality performance category, Table 96 for the Promoting Interoperability performance category, and Table 101 for the improvement activities performance category.

(3) Summary of Quality Payment Program Changes: Advanced APMs

As discussed in more detail in sections VI.B.7. of this final rule, ICRs for Advanced APMs consist of: Partial Qualifying APM Participant (QP) election; Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of data for All-Payer QP determinations under the All-Payer Combination Option.

For these ICRs, the changes to currently approved burden estimates are adjustments based on updated projections for the 2020 MIPS performance period. We are not making any changes to our per-respondent burden estimates and have not made any changes or adjustments to the burden estimates provided in the CY 2020 PFS proposed rule. We are also not making any changes to the Other Payer Advanced APM identification: Eligible Clinician Initiated Process ICR.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 73 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 73, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 73.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. For the 2020 MIPS performance period, the quality data submitted by MIPS APM participants reporting through the CMS Web Interface on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category. For other MIPS APMs, the quality data submitted by APM Entities on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category if that data is available to be scored. However, as finalized in section III.K.3.c.(5)(c)(i)(A) of this rule, beginning in the 2020 MIPS performance period, MIPS eligible clinicians participating in MIPS APMs whose APM quality data is not available for MIPS may elect to report MIPS quality measures at either the APM entity, individual, or TIN-level in a manner similar to our established policy for the Promoting Interoperability performance category under the APM scoring standard for purposes of the MIPS quality performance category. If we determine there are not sufficient measures applicable and available, we will assign performance category weights as specified in § 414.1370(h)(5).

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we described that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Advanced APM participants who are determined to be Partial QPs may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844), but other than the election to participate in MIPS, we do not have data to estimate that burden.

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TABLE 73: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	Promoting Interoperability Performance Category	Improvement Activities Performance Category	Other Data Submitted on Behalf of MIPS Eligible Clinicians
MIPS Eligible Clinicians (not in MIPS APMs) and Other Eligible Clinicians Voluntarily Submitting MIPS Data [a]	As virtual group, group, or individual clinicians	As virtual group, group, or individual clinicians. Clinicians who are hospital-based, ambulatory surgical center-based, non-patient facing, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting.	As virtual group, group, or individual clinicians	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. Virtual groups must register via email.
MIPS Eligible Clinicians Participating in MIPS APMs that report via Web Interface	ACOs submit to the CMS Web Interface and CAHPS for ACOs on behalf of their participating MIPS eligible clinicians. If the ACO does not submit quality data, MIPS eligible clinicians participating in MIPS APMs may elect to report individually or at the TIN-level.[e] [Submissions by the ACO are not included in	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [Burden estimates for this final rule assume group TIN-level reporting].[c]	CMS will assign the improvement activities performance category score to each APM Entity group based on the activities involved in participation in the MIPS APM.[d] [The burden estimates for this final rule assume no improvement activity reporting burden for APM participants because we assume the MIPS	APM Entities will make Partial QP election for participating MIPS eligible clinicians.

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	**Promoting Interoperability Performance Category**	**Improvement Activities Performance Category**	**Other Data Submitted on Behalf of MIPS Eligible Clinicians**
	burden estimates for this final rule because quality data submission to fulfill requirements of the Shared Savings Program and for purposes of testing and evaluating the Next Generation ACO Model are not subject to the PRA].[b]		APM model provides a maximum improvement activity performance category score.]	
MIPS Eligible Clinicians Participating in Other MIPS APMs	APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians; however if the quality data is not available to MIPS in time for scoring, MIPS eligible clinicians participating in MIPS APMs may elect to report individually or at the TIN-level.[e] [Submissions made by APM Entities to MIPS on behalf of their participating MIPS eligible clinicians are not included in burden estimates for this final rule because quality data submission for purposes of testing and evaluating Innovation Center models tested under section	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this final rule assume group TIN-level reporting].	CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM. [The burden estimates for this final rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score.]	APM Entities will make Partial QP election for participating eligible clinicians.

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	Promoting Interoperability Performance Category	Improvement Activities Performance Category	Other Data Submitted on Behalf of MIPS Eligible Clinicians
	1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.]			

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

a Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

b Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA.

c Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

d APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent.(42 CFR 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

e Both group TIN and individual clinician quality data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. We would then use the highest individual or TIN-level score attributable to each MIPS eligible clinician in an APM Entity in order to determine the APM Entity score based on the average of the highest scores for each MIPS eligible clinician in the APM Entity.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 PFS final rule and continued in this final rule create some additional data collection requirements not listed in Table 73. These additional data collections, some of which were previously approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs Related to MIPS Third-Party Intermediaries

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314).
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).

Additional ICRs Related to the Data Submission and the Quality Performance Category

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs Related to the Promoting Interoperability Performance Category

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs Related to Call for New MIPS Measures and Activities

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for new Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).
- Call for new quality measures (83 FR 60010 through 60011) (OMB 0938–1314).

Additional ICRs Related to MIPS

- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs Related to APMs

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule is not finalizing any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under

control number 0938–1343 (CMS–10652). Consequently, we are not making any virtual group election changes under that control number.

c. ICRs Regarding Third-Party Intermediaries (§ 414.1400)

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as either one quality performance category measure, or towards an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nominate process annually. The processes for self-nomination for entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

The burden associated with qualified registry self-nomination, QCDR self-nomination and measure submission, and the CAHPS for MIPS survey vendor applications follow: [130]

(2) Qualified Registry Self-Nomination Applications

The requirements and burden associated with qualified registries and their self-nomination will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As explained below, this rule will both adjust the number of self-nomination applications based on current data and revise the number of self-nomination applications due to policies promulgated in the CY 2019 final rule regarding the definition of a QCDR (83 FR 59895) and minimum participation requirements (83 FR 59897) which are effective beginning in the 2020 MIPS performance period. The adjustment will decrease our total burden estimates while keeping our burden per response estimates unchanged. We are not making any changes to the self-nomination process.

We refer readers to § 414.1400(a)(2) and (c)(1) which state that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so.

In the CY 2018 Quality Payment Program final rule (82 FR 53815) and as stated in § 414.1400(c)(1), previously approved qualified registries in good standing (that is, that are not on probation or disqualified) may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period. In the same rule, we stated that qualified registries in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved qualified registry application for CMS review during the self-nomination period (82 FR 53815). The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period beginning with the 2020 MIPS performance period (83 FR 59906).

For this final rule, we have adjusted the number of self-nominating applicants from 150 to 153 based on the number of applications received during the 2020 self-nomination period, an increase of 3 from the currently approved estimate of 150 (83 FR 59997 through 59998). This is a decrease of 137 from the estimate of 290 provided in the CY 2020 PFS proposed rule due to availability of more recent data. This estimate reflects impacts of revisions to both the definition of a QCDR and minimum participation requirements for entities seeking approval as a QCDR which were previously finalized in the CY 2019 PFS final rule (83 FR 59895 through 59897) that may or may not have resulted in some entities seeking approval as a qualified registry rather than a QCDR.

The burden associated with the qualified registry self-nomination process varies depending on the number of existing qualified registries that elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53815). The Quality Payment Program Self-Nomination Form is submitted electronically using a web-based tool. We will be submitting a revised version of the form for approval under OMB control number 0938–1314 (CMS–10621).

As described in the CY 2017 Quality Payment Program final rule, the full self-nomination process requires the submission of basic information, a description of the process the qualified registry will use for completion of a randomized audit of a subset of data prior to submission, and the provision of a data validation plan along with the results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). As shown in Table 75, we estimate that the staff involved in the qualified registry self-nomination process will be mainly computer systems analysts or their equivalent, who have an adjusted labor rate of $90.02/hr. Consistent with the CY 2019 PFS final rule (83 FR 59998), we estimate that the time associated with the self-nomination process ranges from a minimum of 0.5 hours (for the simplified self-nomination process) to 3 hours (for the full self-nomination process) per qualified registry. For the 2019 MIPS performance period, 135 qualified registries were approved to submit data out of the total 141 (96 percent) which submitted nomination forms. For our minimum burden estimate, we assume a similar percentage of the 153 qualified registries that submitted nomination forms in CY 2019 for the 2020 MIPS performance period will be approved and will nominate using the simplified process in CY 2020; this results in a total of 147 (153 × 96 percent) simplified self-nomination applications received. When considering this rule's adjusted number of nomination applications (153), we estimate that the annual burden will range from 91.5 hours ([147 simplified self-nominations × 0.5 hr] + [6 full self-nominations × 3 hr]) to 459 hours (153 qualified registries × 3 hr) at a cost ranging from $8,237 (91.5 hr × $90.02/hr) to $41,319 (459 hr × $90.02/hr), respectively (see Table 75).

As shown in Table 74, compared to the currently approved minimum estimates of 97.5 hours and $8,777 and the maximum estimates of 450 hours and $40,509, the increase in the number of respondents will adjust our total burden estimates by −6 hours and −$540 [(6 registries × 0.5 hr × $90.02/hr) + (−3 registries × 3 hr × $90.02/hr)] and +9 hours and +$810 (3 registries × 3 hr × $90.02/hr). Although we are adjusting our total burden estimates based on more current data, the burden per response would remain unchanged. The reason for the decrease in minimum burden despite an increase in number of qualified registries, is the change in number of simplified and full self-nominations. In the CY 2019 PFS final rule, we estimate 141 simplified self-

[130] As stated in the CY 2019 PFS final rule (83 FR 53998), health IT vendors are not included in the burden estimates for MIPS.

nominations and 9 full self-nominations; for this final rule, we estimate 147 simplified self-nominations and 6 full self-nominations.

TABLE 74: Change in Estimated Burden for Qualified Registry Self-Nomination

	Minimum Burden	Maximum Burden
Total Annual Hours for Qualified Registries in CY 2019 Final Rule (a)	97.5	450
Total Annual Hours for Qualified Registries in CY 2020 Final Rule (b)	91.5	459
Difference (c) = (b)-(a)	**-6**	**+9**
Total Annual Cost for Qualified Registries in CY 2019 Final Rule (d)	$8,777	$40,509
Total Annual Cost for Qualified Registries in CY 2020 Final Rule (e)	$8,237	$41,319
Difference (f) = (e)-(d)	**$-540**	**+$810**

As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at (83 FR 60088) and in § 414.1400(a)(2), qualified registries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. In section III.K.3.g.(4)(a)(i) of this rule, we are finalizing changes to § 414.1400(a)(2) to state that beginning with the 2023 payment year (2021 performance period), qualified registries must be able to submit data for all of the MIPS performance categories identified in the regulation. We are also finalizing to amend § 414.1400(a)(2)(iii) to state that a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or § 414.1380(c)(2)(i)(C)(*1*) through (*7*) or (*9*). As part of the current self-nomination process, qualified registries are already required to attest to the MIPS quality measures, performance categories, improvement activities, and/or Promoting Interoperability measures and objectives supported. As part of this policy, we are requiring qualified registries to attest to the ability to submit data for all three of these performance categories at time of self-nomination. As finalized in the CY 2017 Quality Payment Program final rule, qualified registries are required to provide feedback on all of the MIPS performance categories at least 4 times a year (81 FR 77367 through 77386). In section III.K.3.g.(4)(a)(ii), we are finalizing, beginning with the 2023 MIPS payment year, to require qualified registries to provide the following as a part of the performance feedback given at least 4 times (to the extent feasible) a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registry. Further, qualified registries will be required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year, and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Because we are not requiring qualified registries to provide performance feedback to their clinicians and groups at a greater frequency than what has previously been required combined with qualified registries only being required to provide feedback using data they are already collecting, we do not believe this finalized policy creates enough additional burden for qualified registries to elect to discontinue participation in the Quality Payment Program. Therefore, we are not adjusting our estimates for the number of qualified registries that will self-nominate in the 2021 performance period or future years as a result of this requirement; if reliable information becomes available indicating this assumption is incorrect, we will adjust our assumptions and respondent estimates at that time. Because qualified registries will only be required to provide performance feedback to clinicians and not to CMS, and because qualified registries are already required to attest to the performance categories they support, we anticipate minimal changes to the self-nomination process as a result of these requirements and assume there will be minimal impact on the time required to complete either the simplified or full self-nomination process.

We are also finalizing in section III.K.3.g.(2) of this final rule and at § 414.1400(a)(4) to establish that a condition of approval is for the third party intermediary to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan. Because of the uncertain, but low frequency (less than 10 per year historically) with which third party intermediaries have elected to discontinue services during a performance period, we are unable to estimate the total burden associated with development of CMS approved transition plans. However, we anticipate the time involved in developing a transition plan and disseminating it to their contracted MIPS eligible clinicians is likely to be no more than 10 hours.

Qualified registries must comply with requirements on the submission of MIPS data to CMS. The burden associated with qualified registry submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. We expect that the time needed for a qualified registry to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry and the number of applicable measures. However, we believe that qualified registries already perform many of these activities for their participants. Therefore, we believe the estimates discussed earlier and shown in Table 75

represents the upper bound for qualified registry burden, with the potential for less additional MIPS burden if the qualified registry already provides similar data submission services.

Based on these assumptions, we estimate the total annual burden associated with a qualified registry self-nominating to be considered for approval.

TABLE 75: Estimated Burden for Qualified Registry Self-Nomination

	Minimum Burden	Maximum Burden
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	147	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	6	153
Total Applications	**153**	**153**
Total Annual Hours Per Qualified Registry for Simplified Process (c)	0.5	0.5
Total Annual Hours Per Qualified Registry for Full Process (d)	3	3
Total Annual Hours (e) = (a)*(c)+(b)*(d)	**91.5**	**459**
Cost Per Simplified Process Per Registry (@ computer systems analyst's labor rate of $90.02/hr.) (f)	$45.01	$45.01
Cost Per Full Process Per Registry (@ computer systems analyst's labor rate of $90.02/hr.) (g)	$270.06	$270.06
Total Annual Cost (h) = (a)*(f)+(b)*(g)	**$8,237**	**$41,319**

Both the minimum and maximum burdens shown in Table 75 reflect adjustments to the number of respondents (from 150 to 153) due to availability of more recent data (+3 respondents). For purposes of calculating total burden associated with this final rule as shown in Table 116 only the maximum burden is being submitted to OMB for their review and approval.

We received no public comments related to the burden estimates for qualified registry self-nomination. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40848 through 40849) due to availability of updated data.

(3) QCDR Self-Nomination Applications

(a) Self-Nomination Process

The requirements and burden associated with QCDRs and the self-nomination process will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As explained below, this rule will adjust the number of self-nomination applications submitted by QCDRs seeking approval to submit data from 200 to 76 based on data from the CY 2019 nomination period for the 2020 MIPS performance period. This estimate reflects impacts of revisions to both the definition of a QCDR and minimum participation requirements for entities seeking approval as a QCDR which were previously finalized in the CY 2019 PFS final rule (83 FR 59895 through 59897) that may or may not have resulted in some entities seeking approval as a qualified registry rather than a QCDR. This rule will also update the number of QCDR measures submitted for consideration by each QCDR seeking to self-nominate (from 9 to 2), as well as the time required to submit information (from 1 hour to 2.5 hours) for each QCDR measure due to policies being finalized. In addition, our per response estimates for the simplified and full self-nomination processes will decrease from 9.5 hours to 5.5 hours and from 12 hours to 8 hours, respectively due strictly to our adjustment to the average number of QCDR measures submitted for approval by each QCDR based on availability of more recent data. These changes will decrease our minimum total burden estimate (from 2,025 hours to 418 hours) and increase our maximum total burden estimate (from 2,400 hours to 608 hours).

We refer readers to § 414.1400(a)(2) and (b)(1) which state that QCDRs interested in submitting MIPS data to us on behalf of a MIPS eligible clinician, group, or virtual group will need to complete a self-nomination process to be considered for approval to do so.

In the CY 2018 Quality Payment Program final rule and § 414.1400(b)(1), previously approved QCDRs in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable (82 FR 53808). Existing QCDRs in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved QCDR application, for CMS review during the current self-nomination period, from September 1 to November 1 (82 FR 53808). The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period beginning in the 2020 MIPS performance period (83 FR 59898).

The burden associated with QCDR self-nomination will vary depending on the number of existing QCDRs that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813). The OPP Self-Nomination Form is submitted electronically using a web-based tool. We will be submitting a revised version of the form for approval under OMB control number 0938–1314 (CMS–10621).

For this final rule, we have adjusted the number of QCDRs self-nominating for approval to submit data from 200 to 76 based on the number of applications received during the CY 2019 self-nomination period for the 2020 MIPS performance period, a decrease of 124 from the currently approved estimate of 150 (83 FR 59997 through 59998). This is a decrease of 15 from the estimate of 91 provided in the CY 2020 PFS proposed rule due to availability of more recent data. Given this decrease, for our minimum burden estimate we will assume each of the 76 QCDRs will be approved for the 2020 MIPS performance period and will self-nominate using the simplified process during the CY 2020 nomination period. This estimate reflects impacts of revisions to both the definition of a QCDR and minimum participation requirements for entities seeking approval as a QCDR which were previously finalized in the CY 2019 PFS final rule (83 FR 59895 through 59897) that may or may not have resulted in

some entities seeking approval as a qualified registry rather than a QCDR. We were unable to change our estimates in the CY 2019 PFS final rule to reflect these policies because we had neither the data to support a change nor any notifications of intent by previously approved QCDRs indicating they would no longer self-nominate as a QCDR (83 FR 59999). As a result, we are making the necessary adjustments to our respondent estimates in this final rule.

Based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088), the current policy is that all third party intermediaries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. In section III.K.3.g.(3)(a)(i) of this rule, we are finalizing changes to § 414.1400(a)(2) to state that beginning with the 2023 MIPS payment year (2021 performance period), QCDRs must be able to submit data for all of the MIPS performance categories identified in the regulation. We are also finalizing to amend § 414.1400(a)(2)(iii) to state that for the Promoting Interoperability performance category, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(*A*)(*4*) or (5) or § 414.1380(c)(2)(i)(*C*)(*1*) through (*7*) or (*9*). As finalized in the CY 2018 Quality Payment Program final rule, QCDRs are required to provide feedback on all of the MIPS performance categories that the QCDR reports at least 4 times a year (82 FR 53812). In section III.K.3.g.(3)(a)(iii) we are finalizing, beginning with the 2023 MIPS payment year, to require that QCDRs provide the following as a part of the performance feedback given at least 4 times a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure and/or QCDR measure) within the QCDR. We also understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. Further, we are also finalizing, beginning with the 2023 MIPS payment year, to require QCDRs to attest during the self-nomination process that they can provide performance feedback at least 4 times a year, and if not, provide sufficient rationale as to why they do not believe they will be able to meet this requirement. We do not believe these proposals create enough additional burden for QCDRs to elect to discontinue participation in the Quality Payment Program because we are not requiring QCDRs to provide performance feedback to their clinicians and groups at a greater frequency than what has previously been required and because QCDRs will only be required to provide feedback using data they are already collecting. Therefore, we are not adjusting our estimates for the number of QCDRs that will self-nominate in the 2021 performance period or future years as a result of these finalized policies; if reliable information becomes available indicating this assumption is incorrect, we will adjust our assumptions and respondent estimates at that time. As part of the self-nomination process, QCDRs are already required to attest to the MIPS quality measures, performance categories, improvement activities, and Promoting Interoperability measures and objectives supported and will not be required to provide performance feedback to CMS. Therefore, we anticipate no additional steps being added to the self-nomination process as a result of these finalized policies and assume there will be no impact on the time required to complete either the simplified or full self-nomination process.

In the CY 2020 PFS proposed rule, we increased our per-respondent burden estimate for completing the full self-nomination process by 15 minutes (0.25 hours) due to the proposal to require QCDRs to describe the quality improvement services they will provide as part of their self-nomination (84 FR 40851). Due to this proposal not being finalized, we have decreased our burden estimate from the CY 2020 PFS proposed rule by 0.25 hours.

We estimate that the self-nomination process for QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 3 hours per QCDR to submit information required at the time of self-nomination as described in the CY 2017 Quality Payment Program final rule including basic information about the QCDR, describing the process it will use for completion of a randomized audit of a subset of data prior to submission, providing a data validation plan, and providing results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). However, for the simplified self-nomination process, we estimate 0.5 hours per QCDR to submit this information.

We are also finalizing in section III.K.3.g.(2) of this final rule and at § 414.1400(a)(4) to establish that a condition of approval is for the third party intermediary to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan. Because of the uncertain, but low frequency (less than 10 per year historically) with which third party intermediaries have elected to discontinue services during a performance period, we are unable to estimate the total burden associated with development of CMS approved transition plans. However, we anticipate the time involved in developing a transition plan and disseminating it to contracted MIPS eligible clinicians is likely to be no more than 10 hours.

(b) QCDR Measure Requirements

As promulgated in the CY 2017 and CY 2018 Quality Payment Plan final rules (81 FR 77366 through 77374 and 82 FR 53812 through 53813), QCDRs calculate their measure results and also must possess benchmarking capabilities (for QCDR measures) that compare the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For QCDR measures, the QCDR must provide to us, if available, data from years prior (for example, 2017 data for the 2019 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide to us, if available, the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their website prior to the start of the performance period, to the extent permitted by applicable privacy laws. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a QCDR will spend an additional 1 hour performing these activities per measure.

As discussed in section III.K.3.g.(3)(c)(i)(B)(cc), we are finalizing that in order for a QCDR measure to be considered for use in the program beginning with the 2021 performance period and future years, all QCDR measures submitted for self-nomination

must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System, as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. Beginning with the 2021 performance period and future years, we are finalizing in section III.K.3.g.(3)(c)(i)(B)(dd) of this final rule, to also require QCDRs to collect data on the potential QCDR measure, appropriate to the measure type, as defined in the CMS Blueprint for the CMS Measures Management System, prior to self-nomination. We estimate the time necessary to submit measure testing data as part of the self-nomination process will average approximately 0.5 hours per measure, understanding that this estimate may be either high or low depending on the type of measure and the quantity of data being submitted. We discuss additional impacts of this proposal in section VII.C.10.(f) of this rule's RIA.

In section III.K.3.g.(3)(c)(i)(A)(bb) of this rule, we are finalizing to amend § 414.1400 to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. Because the choice to license a QCDR measure is an elective business decision made by individual QCDRs and we lack insight into both the specific terms and frequency of agreements made between entities, we are not accounting for QCDR measure licensing costs as part of our burden estimate. However, if information regarding the number of licensing agreements and the approximate cost per agreement becomes available, we may adjust our assumptions and burden estimates at that time.

In section III.K.3.g.(3)(c)(i)(B)(ee) of this rule, we are finalizing, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. We are unable to account for measure harmonization costs as part of our burden estimate, as the process and outcomes of measure harmonization will likely vary substantially depending on a number of factors, including: Extent of duplication with other measures, number of QCDRs involved in harmonizing toward a single measure, and number of measures being harmonized among the same QCDRs. We intend to identify only those QCDR measures which are duplicative to such an extent as to assume harmonization will not be overly burdensome, however, because the harmonization process will occur between QCDRs without our involvement, we are unable to predict or quantify the associated effort.

As discussed in section III.K.3.g.(3)(c)(i)(B)(bb) of this final rule, beginning with the 2021 performance period and future years, we are finalizing that QCDRs are required to link their QCDR measures as feasible to at least one of the following, at the time of self-nomination: (1) Cost measures (as found in section III.K.3.c.(2) of this final rule); (2) improvement activities (as found in Appendix 2: Improvement Activities Tables); or (3) CMS developed MIPS Value Pathways (as described in section III.K.3.a. of this final rule). We estimate that a QCDR will spend an additional 1 hour performing these activities per measure, on average.

We are also finalizing to formalize factors we would take into consideration for approving and rejecting QCDR measures for the MIPS program beginning with the 2022 MIPS payment year (2020 performance period). With regard to approving QCDR measures, we are finalizing the following: (a) 2-year QCDR measure approval process, and (b) participation plan for existing QCDR measures that have failed to reach benchmarking thresholds. As discussed in section III.K.3.g.(3)(c)(ii)(B) of this rule, we are finalizing to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described in section III.K.3.g.(3)(c). The 2-year approvals will be subject to the following conditions whereby the multi-year approval will no longer apply if the QCDR measure is identified as: Topped out; duplicative of a new, more robust measure; reflects an outdated clinical guideline; requires measure harmonization, or if the QCDR self-nominating the measure is no longer in good standing. We believe this could result in reduced burden for QCDRs as they would not necessarily be required to submit every measure for approval annually. However, because we are unable to predict which previously approved QCDR measures will be removed or retained in future years, we are likewise unable to predict the total number of measures that will be submitted for approval and the resulting impact on future burden. We anticipate that the number of QCDR measures submitted in the 2021 performance period will reflect the impact of this policy; at that time we will update our assumptions and burden estimates accordingly.

We estimate that on average, each QCDR will submit information for 2 QCDR measures, for a total burden of 2 hours per QCDR (1 hr per measure × 2 measures). Based on the number of measures nominated during the CY 2019 nomination period for the 2020 MIPS performance period (790, or approximately 10.4 measures per QCDR) as well as an analysis of currently approved QCDR measures which indicates less than 10 percent of current measures have completed testing, we believe each QCDR is likely to submit 1 previously approved QCDR measure for approval during the CY 2020 nomination period. We also believe the finalized policy requiring measure testing will result in additional measures undergoing testing than in previous years and therefore estimate each QCDR will submit 1 additional measure for approval during the CY 2020 nomination period, for a total of 2 measures per QCDR. Finally, we believe the finalized changes in requirements for QCDR measure submission and for QCDRs to harmonize measures we identify as duplicative discussed earlier in this section will result in a reduction in the number of QCDR measures submitted for approval in future years. However, we are unable to quantify the impact these changes will have on the number of measures QCDRs will submit for approval beyond the impacts previously discussed. As information becomes available in future years, we will revisit our assumptions to better reflect the impact of these requirements on QCDRs and the quantity of measures

being submitted for consideration annually. When combined with our previously stated assumption regarding our inability to predict which QCDR measures will maintain approval in future years, we believe the estimate of 2 measures per QCDR to be appropriate.

Beginning with the 2021 performance period, we are finalizing in section III.K.3.g.(3)(c)(iii) of this rule that in instances where an existing QCDR measure has been in MIPS for 2 years, and has failed to reach benchmarking thresholds due to low adoption, where a QCDR believes the low-reported QCDR measure is still important and relevant to a specialist's practice, that the QCDR may develop and submit to a QCDR measure participation plan, to be submitted as part of their self-nomination. Because we are unable to predict the frequency with which existing QCDR measures will meet the finalized criteria for allowing QCDRs to submit a measure participation plan or the likelihood of QCDRs electing to submit a plan, we are unable to estimate the total associated burden. However, we anticipate the time involved in developing a measure participation plan is likely to average between 1 and 2 hours, depending on the QCDR and the level of detail they choose to include. In future performance periods we may reassess availability of the number of QCDR measure participation plans submitted by QCDRs and estimate the associated burden, if possible. In aggregate, we estimate a QCDR will require 2.5 hours per QCDR measure, an increase of 1.5 hours from the currently approved estimate of 1 hour (83 FR 59999). As discussed earlier in this section, we estimate each QCDR will submit 2 QCDR measures for approval, on average. Therefore, we estimate each QCDR will require 5 hours (2 measures × 2.5 hr per measure) to submit QCDR measures for approval, independent of the selection of the simplified or full self-nomination process.

We are finalizing in section III.K.3.g.3(c)(i)(A)(bb)(BB) of this final rule, to amend § 414.1400 to add paragraph (b)(3)(iv)(I) to state that we would give greater consideration to measures for which QCDRs: (a) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and (b) utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development. We are also finalizing in section III.K.3.g.3(c)(i)(A)(bb)(CC) of this final rule and § 414.1400 to add paragraph (b)(3)(iv)(J), to state that, beginning with the 2020 performance period, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not meet this requirement, may not continue to be approved. Lastly, we are finalizing in section III.K.3.g.3(c)(i)(B)(aa) of this final rule, beginning with the 2020 performance period, to change both of the below listed considerations into requirements and add § 414.1400(b)(3)(v) to include the following for QCDR measure requirements for approval: Measures that are beyond the measure concept phase of development; and measures that address significant variation in performance. Because these proposals do not impact the amount of information QCDRs are required to submit for the nomination of a QCDR measure, we are not finalizing any additional changes to our burden estimate as result of these policies. We also do not believe these policies are likely to result in any additional change in the number of measures submitted per QCDR beyond the impacts previously discussed.

In the CY 2019 PFS final rule, the burden associated with self-nomination of a QCDR was estimated to range from a minimum of 9.5 hours (0.5 hours to submit information for simplified self-nomination process and 9 hours for submission of QCDR measures) to a maximum of 12 hours (3 hours for the full self-nomination process and 9 hours for the submission of QCDR measures) (83 FR 59999). For this rule, we are finalizing to increase the burden associated with self-nomination to a minimum of 5.5 hours (0.5 hours to submit information for the simplified self-nomination process and 5 hours for the submission of QCDR measures) to a maximum of 8 hours (3 hours to submit information for the full self-nomination process and 5 hours for the submission of QCDR measures) to account for our revised estimate of the average number of QCDR measures submitted for consideration per QCDR, as well as the revised estimate of burden per QCDR measure.

We assume that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $90.02/hr. Considering that the time per QCDR associated with the self-nomination process ranges from a minimum of 5.5 hours to a maximum of 8 hours, we estimate that the annual burden will range from 418 hours (76 QCDRs × 5.5 hr) to 608 hours (76 QCDRs × 8 hr) at a cost ranging from $37,628 (418 hr × $90.02/hr) and $54,732 (608 hr × $90.02/hr), respectively (*see* Table 76).

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 76: Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

	Minimum	Maximum
# of QCDR Simplified Self-Nomination Applications submitted (a)	76	0
# of QCDR Full Self-Nomination Applications submitted (b)	0	76
Total Applications	**76**	**76**
Total Annual Hours Per QCDR for Simplified Process (c)		
Total Annual Hours Per QCDR for Full Process (d)	5.5	5.5
Total Annual Hours (e) = (a)*(c) + (b)*(d)	8	8
Cost Per Simplified Process Per QCDR (@ computer systems analyst's labor rate of $90.02/hr) (f)	**418**	**608**
Cost Per Full Process Per QCDR (@ computer systems analyst's labor rate of $90.02/hr) (g)	$495.11	$495.11
Total Annual Cost (h) = (a)*(f)+(b)*(g)	$720.16	$720.16
	$37,628	**$54,732**

Both the minimum and maximum burden shown in Table 76 reflect adjustments to the number of respondents due to availability of more recent data, as well as changes resulting from policies finalized in the CY 2019 PFS final rule regarding the definition and minimum participation requirements for entities seeking approval as QCDRs which will be effective beginning with the 2020 MIPS performance period. For purposes of calculating total burden associated with the final rule as shown in Table 116, only the maximum burden is used.

Independent of the change to our per response time estimate, the decrease in the number of respondents (from 200 to 76) results in an adjustment of between −1,303 hours [(−74 QCDRs × 9.5 hr) + (−50 QCDRs × 12 hr)] at a cost of −$117,297 (−1,303 hr × $90.02) and −1,488 hours (−124 QCDRs × 12 hr) at a cost of −$133,950 (−1,488 hr × $90.02/hr). Accounting for the adjustment in the number of QCDRs, the change in time per QCDR to self-nominate results in an change of between −304 hours (76 QCDRs × −4 hr) at a cost of −$27,366 (−304 hr × $90.02/hr) and −304 hours (76 QCDRs × −4 hr) at a cost of −$27,366 (−304 hr × $90.02/hr). As shown in Table 77, when these two adjustments are combined, the net impact ranges between −1,607 hours (−1,304 hr −304 hr) at a cost of −$144,663 (−$117,297 −$27,366) and −1,792 hours (−1,488 hr −304 hr) at a cost of −$161,316 (−$133,950 −$27,366).

TABLE 77: Change in Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

	Minimum Burden	Maximum Burden
Total Annual Hours for QCDRs in CY 2019 Final Rule (a)	2,025	2,400
Total Annual Hours for QCDRs in CY 2020 Final Rule (b)	418	608
Difference (c) = (b)-(a)	**-1,607**	**-1,792**
Total Annual Cost for QCDRs in CY 2019 Final Rule (d)	$182,291	$216,048
Total Annual Cost for QCDRs in CY 2020 Final Rule (e)	$37,628	$54,732
Difference (f) = (e)-(d)	**-$144,663**	**-$161,316**

QCDRs must comply with requirements on the submission of MIPS data to CMS. The burden associated with the QCDR submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the QCDR by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. We expect that the time needed for a QCDR to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the QCDR and the number of applicable measures. However, we believe that QCDRs already perform many of these activities for their participants. As stated in section III.K.3.g.(3)(a)(i), based on our review of existing 2019 QCDRs through the 2019 QCDR Qualified Posting, approximately 92 QCDRs, or about 72 percent of the QCDRs currently participating in the program are able to submit data for these three performance categories. In addition, through our review of previous qualified postings for the 2018 and 2017 MIPS performance periods, we have observed that in 2018, 73 percent (approximately 110 QCDRs) and in 2017, 73 percent (approximately 83 QCDRs) have been able to submit data for all three of the quality, Promoting Interoperability, and improvement activity performance categories. Given this, we believe it is reasonable that all QCDRs have the capacity to submit data for the improvement activities and Promoting Interoperability performance categories and are not making any further changes to our burden estimates. Therefore, we believe the 608 hour estimate noted in this section represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar data submission services.

The following is a summary of the public comments received on the Quality Payment Program ICRs regarding the burden estimates for QCDR self-nomination.

Comment: A few commenters believe that the scope of proposals in the proposed rule increases cost and burden to the point where some third-party intermediaries may end their participation in MIPS. One commenter stated that several provisions would additionally require it to alter business plans, missions, and customer service priorities while another commenter cited their belief that CMS is attempting to shift costs and burden of administering the MIPS program onto specialty societies that create measures and operate QCDRs.

Response: We believe that our policies are intended to standardize and raise the bar on the services and the quality of the third party intermediaries we have in the MIPS program. Similar to years past, the standards and requirements of QCDRs are higher when compared to that of qualified registries, as we expect QCDRs to have extensive experience in quality reporting, quality measure development, and clinical expertise to not just facilitate reporting, but to also help address measurement gaps found within the program. We believe that QCDRs and qualified registries should further clinician goals of quality improvement by providing meaningful information and services. While we estimate increases in the burden for self-nomination, the burden per QCDR measure submitted for approval, and the costs associated with developing measures and meeting requirements for approval as a QCDR or registry, we believe that the increased cost and burden are significantly outweighed by the positive impact of the policies for MIPS eligible clinicians. We discuss the financial impact of these proposals beyond reporting burden further in section VII.F.10.f. of the RIA.

Comment: One commenter believes that the ''true costs'' associated with a QCDR application, whether using the simplified or full application, must reflect more than the actual time to input the data required. The commenter further cited costs such as creating and maintaining registries and QCDR

measures, recruitment of clinicians to develop quality improvement initiatives, hiring staff to support and develop content and services identified by these clinicians, and technology solutions necessary to support the quality improvement services.

Response: We recognize there are additional costs and administrative burdens on respondents associated with self-nominating as a QCDR or submitting a QCDR measure beyond the reporting burden estimated in the Collection of Information section of this policy which only accounts for the time required for record keeping, reporting, and third-party disclosures associated with the policy. We discuss the financial impact of these proposals beyond reporting burden further in section VII.F.10.f. of the RIA. We understand that some respondents may require additional time above the 0.5 hours we estimate for the simplified self-nomination process and the 3 hours for the full self-nomination process, but given that we do not include the costs to maintain registries or create measures and quality improvement services in our burden estimate, we believe this estimate is a reasonable average across all respondents based on our review of the nomination process, the information required to complete the nomination form, and the criteria required to self-nominate as a QCDR.

After consideration of public comments, we are making no changes to our estimates as a result of public comments received, however we have decreased our per-respondent burden estimate for completing the full self-nomination form by 0.25 hours due to the decision not to finalize the proposal to require QCDR to engage in activities that will foster improvement in the quality of care. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40850 through 40854) due to availability of updated data.

(4) CAHPS for MIPS Survey Vendor

This rule is not finalizing any new or revised collection of information requirements or burden related to CMS-approved CAHPS for MIPS survey vendors. The requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any MIPS survey vendor changes under that control number.

d. ICRs Regarding Quality Data Submission (§§ 414.1325 and 414.1335)

(1) Background

As explained below, this rule will adjust the number of respondents based on current data. The adjustment will increase our total burden estimates while keeping our ''per response'' estimates unchanged. We are not revising any requirements regarding the number of measures to be submitted or the manner in which they may be submitted.

Under our current policies, two groups of clinicians must submit quality data under MIPS: Those who submit as MIPS eligible clinicians and those who opt to submit data voluntarily but are not subject to MIPS payment adjustments.

Clinicians are ineligible for MIPS if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

To determine which QPs should be excluded from MIPS, we used the QP List for the 2019 predictive file that contains current participation in Advanced APMs as of January 15, 2019, that could be connected into our respondent data and are the best estimate of future expected QPs. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2020 QP performance period. We assumed that all partial QPs will participate in MIPS data collections. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future 2020 Medicare QP Performance Period (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

Using participation data from the 2018 MIPS performance period combined with the estimate of QPs for the 2020 performance period, we estimate a total of 780,605 clinicians will submit quality data as individuals or groups in the 2020 MIPS performance period, a decrease of 183,641 clinicians when compared to our estimate of 964,246 clinicians in the CY 2019 PFS final rule (83 FR 60002).

In the CY 2017 Quality Payment Program final rule, we assumed that any clinician that submits quality data codes to us for the Medicare Part B claims collection type is intending to do so for the Quality Payment Program to ensure that we fully accounted for any burden that may have resulted from our policies (81 FR 77501 through 77504); we continued using this assumption in both the CY 2018 Quality Payment Program final rule and the CY 2019 PFS final rule. In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752). However, we also elected to continue using the assumption that all clinicians (except QPs) who submitted data via the Medicare Part B claims collection type in the 2018 MIPS performance period would continue to do so for MIPS to avoid overstating the impact of the change as we lacked the data to accurately estimate both the number of clinicians who would be impacted by the finalized policies and the potential behavioral response of those clinicians who would be required to switch to another collection type (83 FR 60001). For this final rule, beginning with the 2020 MIPS performance period, we assume only clinicians in small practices who submitted quality data via Medicare Part B claims in the 2018 MIPS performance period will continue to do so for the 2020 MIPS performance period. Further, we assume that clinicians in other practices (not small practices) who meet at least one of the following criteria will not need to find an alternate collection type for submitting quality performance category data for the Quality Payment Program for the 2020 MIPS performance period: (1) Facility-based; (2) submitted quality data via Medicare Part B claims and at least one other collection type; or (3) were previously scored as part of a group. Finally, we assume clinicians in other practices (not small practices) who meet all of the following criteria will submit via the MIPS CQM collection type for the 2020 MIPS performance period because the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data: (1) Scored as individuals; (2) not facility-based; and (3) submitted quality data only via the Medicare Part B claims collection type in the 2018 MIPS performance period. Because we do not have data to accurately predict what collection type each affected clinician would use to collect and report quality data, we assume that the affected clinicians will select the MIPS CQM collection type because, when compared to Medicare Part B claims, we believe this is the next most accessible and least burdensome

alternative. Our assumptions result in a 103,103 decrease in the estimated number of clinicians who will submit quality data via Medicare Part B claims and a 12,931 increase in the number of clinicians who will submit via the QCDR/MIPS CQM collection type, as shown in Table 78.

We assume that 100 percent of APM Entities in MIPS APMs will submit quality data to CMS as required under their models. Consistent with assumptions used in the CY 2019 PFS final rule (83 FR 60000 through 60001), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. Therefore, we are not finalizing any adjustments to our respondent estimates as a result of the policies discussed in section III.K.3.c.(5)(c)(i)(A) of this final rule, which allows MIPS eligible clinicians participating in MIPS APMs to elect to report MIPS quality measures at either the individual or TIN-level under the APM scoring standard beginning in the 2020 MIPS performance period. To estimate who will be a MIPS APM participant in the 2020 MIPS performance period, we used the latest QP List for the first snapshot data of the 2019 QP performance period. This file was selected to better reflect the expected increase in the number of MIPS APMs in future years compared to previous APM eligibility files. If a MIPS eligible clinician is determined to not be scored as a MIPS APM, then their reporting assumption is based on their reporting for the CY 2018 MIPS performance period. For clinicians who participated in an APM in 2018, were not in an APM in 2019, and did not report MIPS quality data in 2018, we assume they will elect to report to MIPS via the MIPS CQM collection type, similar to our previously stated assumption regarding clinicians who are required to use an alternate reporting option.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The burden is excluded as sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[131] Tables 78, 79 and 80 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 78 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2020 MIPS performance period based on data from the 2018 MIPS performance period.

For the 2020 MIPS performance period, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and CMS Web Interface. We estimate the burden for collecting data via collection type: Claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintain consistency with previous rulemaking.

For an individual, group, or third-party to submit MIPS quality, improvement activities, or Promoting Interoperability performance category data using either the log in and upload or the log in and attest submission type or to access feedback reports, the submitter must have a CMS Enterprise Portal user account. Once the user account is created using the Identity Management Application Process, registration is not required again for future years.

Table 78 shows that in the 2020 MIPS performance period, an estimated 94,846 clinicians will submit data as individuals for the Medicare Part B claims collection type; 391,430 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; 247,856 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 46,473 clinicians will submit as part of groups via the CMS Web Interface. In the CY 2020 PFS proposed rule, we estimated 109,951 clinicians will submit data as individuals for the Medicare Part B claims collection type; 359,621 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; 247,329 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 116,342 clinicians will submit as part of groups via the CMS Web Interface (84 FR 40856). Our updated estimates reflect the availability of more recent data.

Table 78 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

TABLE 78—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE

	Medicare Part B claims	QCDR/ MIPS CQM	eCQM	CMS web interface	Total
Number of clinicians to collect data by collection type (as individual clinicians or groups) in 2020 MIPS performance period (excludes QPs) (a)	94,846	391,430	247,856	46,473	780,605
* Number of clinicians to collect data by collection type (as individual clinicians or groups) in 2019 MIPS performance period (excludes QPs) (b)	257,260	324,693	243,062	139,231	964,246
Difference (c) = (a) − (b)	−162,414	+66,737	+4,794	−92,758	−183,641

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

[131] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

In the CY 2018 Quality Payment Program final rule (82 FR 53625 through 53626), beginning with the 2019 MIPS performance period, we allowed MIPS eligible clinicians to submit data for multiple collection types for a single performance category. Therefore, with the exception of clinicians not in small practices who previously submitted quality data via Medicare Part B claims, we captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types. Hence, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the 2018 MIPS performance period.

Table 79 uses methods similar to those described to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the 2020 MIPS performance period. We estimate that approximately 94,846 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 100,269 clinicians will submit data as individuals using MIPS CQMs or QCDR collection types; and approximately 38,935 clinicians will submit data as individuals using eCQMs collection type. In the CY 2020 PFS proposed rule, we estimated that 109,951 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 106,039 clinicians will submit data as individuals using MIPS CQMs or QCDR collection types; and approximately 47,455 clinicians will submit data as individuals using eCQMs collection type (84 FR 40856 through 40857). Our updated estimates reflect the availability of more recent data.

TABLE 79—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA AS INDIVIDUALS BY COLLECTION TYPE

	Medicare Part B claims	QCDR/ MIPS CQM	eCQM	CMS web interface	Total
Number of Clinicians to submit data as individuals in 2020 MIPS Performance Period (excludes QPs) (a)	95,846	100,269	38,935	0	234,050
* Number of Clinicians to submit data as individuals in 2019 MIPS Performance Period (excludes QPs) (b)	257,260	71,439	47,557	0	376,256
Difference (c) = (a) − (b)	−162,414	+28,830	−8,622	0	−142,206

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 79 are not mutually exclusive.

Table 80 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2020 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. With the previously discussed exceptions regarding groups who experienced a change in APM participation status between the 2018 and 2019 MIPS performance periods, we assume that groups that submitted quality data as groups in the 2018 MIPS performance period will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the 2020 MIPS performance period. Specifically, we estimate that 10,949 groups and virtual groups will submit data for the QCDR or MIPS CQM collection types on behalf of 291,161 clinicians; 4,398 groups and virtual groups will submit for eCQM collection types on behalf of 208,921 eligible clinicians; and 104 groups will submit data via the CMS Web Interface on behalf of 46,473 clinicians. In the CY 2020 PFS proposed rule, we estimated that 10,552 groups and virtual groups will submit data for the QCDR or MIPS CQM collection types on behalf of 253,582 clinicians; 4,332 groups and virtual groups will submit for eCQM collection types on behalf of 199,874 eligible clinicians; and 104 groups will submit data via the CMS Web Interface on behalf of 116,342 clinicians (84 FR 40857). Our updated estimates reflect availability of more recent data. In the CY 2017 and CY 2018 Quality Payment Program final rules, the CY 2019 PFS final rule, the CY 2020 PFS proposed rule, we were required to adjust our respondent estimates to account for MIPS eligible clinicians who we assumed would respond as participants in a virtual group. Because we are now able to base our respondent estimates on data from the 2018 MIPS performance period, which was the first performance period in which clinicians could submit as participants in a virtual group, we are no longer making the adjustment for virtual group participation.

TABLE 80—ESTIMATED NUMBER OF GROUPS AND VIRTUAL GROUPS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE ON BEHALF OF CLINICIANS

	Medicare Part B claims	QCDR/ MIPS CQM	eCQM	CMS web interface	Total
Number of groups to collect data by collection type (on behalf of clinicians) in 2020 MIPS performance period (excludes QPs) (a)	0	10,949	4,398	104	15,451
* Number of groups to collect data by collection type on behalf of clinicians in 2019 MIPS performance period (b)	0	10,542	4,304	286	15,132

TABLE 80—ESTIMATED NUMBER OF GROUPS AND VIRTUAL GROUPS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE ON BEHALF OF CLINICIANS—Continued

	Medicare Part B claims	QCDR/ MIPS CQM	eCQM	CMS web interface	Total
Difference (c) = (a) − (b)	0	+407	+94	−182	319

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

The burden associated with the submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. In terms of the quality measures available for clinicians and groups to report for the 2020 MIPS performance period, the total number of quality measures will be 218. The new MIPS quality measures proposed for inclusion in MIPS for the 2020 MIPS performance period and future years are found in Table Group A of Appendix 1; MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 81, as well as counts of new, removed, and substantively changed measures.

TABLE 81—SUMMARY OF QUALITY MEASURES FOR THE 2020 MIPS PERFORMANCE PERIOD

Collection type	Number of measures finalized as new	Number of measures finalized for removal	Number of measures finalized with a substantive change	Number of measures remaining for CY 2020 *
Medicare Part B Claims Specifications	0	9	19	55
MIPS CQMs Specifications	2	39	72	196
eCQM Specifications	1	4	34	47
Survey—CSV	0	0	0	1
CMS Web Interface Measure Specifications	0	0	9	10
Administrative Claims	0	0	0	1
Total	3	42	83	218

* A measure may be specified under multiple collection types but will only be counted once in the total.

For the 2020 MIPS performance period, there is a net reduction of 39 quality measures across all collection types compared to the 257 measures finalized for the 2019 MIPS performance period (83 FR 60003). We do not anticipate that removing these measures will increase or decrease the reporting burden on clinicians and groups as respondents are still required to submit quality data for 6 measures.

As discussed in section III.K.3.c.(1)(c)(ii) of this rule, we proposed to adopt a higher data completeness threshold (the percentage of eligible patients the clinician must check to see whether the measure applies to) for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, and eCQMs must submit data on at least 70 percent of the MIPS eligible clinician or group's patients that meet the denominator criteria, regardless of payer for the 2020 MIPS performance period. We believe this proposal may increase administrative burden for some clinicians as it affects the amount of data they have to collect, but will have no impact on regulatory burden as it affects neither the number of quality measures they are required to report nor the amount of data they must report for each quality measure once results have been aggregated.

(2) Quality Payment Program Identity Management Application Process

This rule is not finalizing any new or revised collection of information requirements or burden related to the identity management application process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any identity management application process changes under that control number.

(3) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

This rule is not finalizing any new or revised collection of information

requirements related to the submission of Medicare Part B claims data for the quality performance category. However, we are making adjustments to our currently approved burden estimates based on more recent data. The requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Table 78, based on 2018 MIPS performance period data, we assume that 94,846 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. This rule is finalizing to adjust the number of Medicare Part B claims respondents from 257,260 to 94,846 (a decrease of 162,414) based on more recent data and our updated methodology of accounting only for clinicians in small practices who submitted such claims data in the 2018 MIPS performance period rather than all clinicians who submitted quality data codes to us for the Medicare Part B claims collection type. This is a decrease of 15,105 from the CY 2020 PFS proposed rule estimate of 109,951 respondents due to availability of more recent data (84 FR 40858 through 40859). We continue to anticipate that the Medicare Part B claims submission process for MIPS is operationally similar to the way the claims submission process functioned under the PQRS. Specifically, clinicians will need to gather the required information, select the appropriate QDCs, and include the appropriate QDCs on the Medicare Part B claims they submit for payment. Clinicians will collect QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved by OMB under control number 0938–1197. This final rule's provisions do not necessitate the revision of either form and we made no changes to the associated estimate of reporting burden.

As shown in Table 82, consistent with our currently approved per respondent burden estimates, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours at a cost of $13.50 (0.15 hr × $90.02/hr) to 7.2 hours at a cost of $648.14 (7.2 hr × $90.02/hr) per respondent. The burden will involve becoming familiar with MIPS data submission requirements. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $109.36/hr for a practice administrator, 1 hour at $202.86/hr for a clinician, 1 hour at $45.24/hr for an LPN/medical assistant, 1 hour at $90.02/hr for a computer systems analyst, and 1 hour at $38.00/hr for a billing clerk. We are not revising our currently approved per response burden estimates.

The estimate for reviewing and incorporating measure specifications for the claims collection type is higher than that of QCDRs/Registries or eCQM collection types due to the more manual, and therefore, more burdensome nature of Medicare Part B claims measures.

Considering both data submission and start-up requirements, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual time ranges from 678,149 hours (7.15 hr × 94,846 clinicians) to 1,346,813 hours (14.2 hr × 94,846 clinicians). The estimated annual cost (per clinician) ranges from $717.70 [(0.15 hr × $90.02/hr) + (3 hr × $109.36/hr) + (1 hr × $90.02/hr) + (1 hr × $45.24/hr) + (1 hr × $38.00/hr + (1 hr × $202.86/hr)] to a maximum of $1,352.34 [(7.2 hr × $90.02/hr) + (3 hr × $109.36/hr) + (1 hr × $90.02/hr) + (1 hr × $45.24/hr) + (1 hr × $38.00/hr + (1 hr × $202.86/hr)]. The total annual cost ranges from a minimum of $68,071,259 (94,846 clinicians × $717.70) to a maximum of $128,264,419 (94,846 clinicians × $1,352.34).

Table 82 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims.

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TABLE 82: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden
# of Clinicians (a)	94,846	94,846	94,846
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Practice Administrator Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Clinician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b)+(c)+(d)+(e)+(f)+(g)	7.15	8.05	14.2
Total Annual Hours (i) = (a)*(h)	**678,149**	**763,510**	**1,346,813**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $90.02/hr) (j)	$13.50	$94.52	$648.14
Cost to Review Measure Specifications (@ practice administrator's labor rate of $109.36/hr) (k)	$328.08	$328.08	$328.08
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $90.02/hr) (l)	$90.02	$90.02	$90.02
Cost to Review Measure Specifications (@ LPN's labor rate of $45.24/hr) (m)	$45.24	$45.24	$45.24
Cost to Review Measure Specifications (@ billing clerk's labor rate of $38.00/hr) (n)	$38.00	$38.00	$38.00
Cost to Review Measure Specifications (@ physician's labor rate of $202.86/hr) (o)	$202.86	$202.86	$202.86
Total Annual Cost Per Clinician (p) = (j)+(k)+(l)+(m)+(n)+(o)	$717.70	$798.72	$1,352.34
Total Annual Cost (q) = (a)*(p)	**$68,071,259**	**$75,755,492**	**$128,264,419**

As shown in Table 83, using the unchanged currently approved per respondent burden estimates which range from $717.70 to $1,352.34, the decrease in number of respondents from 257,260 to 94,846 results in a total adjustment of between −1,161,260 hours (−162,414 respondents × 7.15 hr/respondent) at a cost of −$116,565,015 (−162,414 respondents × $717.70/respondent) and −2,306,279 hours (−162,414 respondents × 14.2 hr/respondent) at a cost of −$219,639,598 (−162,414 respondents × $1,352.34/respondent). For purposes of calculating total burden associated with the final rule as shown in Table 116, only the maximum burden is used.

TABLE 83: Change in Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	1,839,409	2,070,943	3,653,092
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	678,149	763,510	1,346,813
Difference (c) = (b)-(a)	**-1,161,260**	**-1,307,433**	**-2,306,279**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$184,636,274	$205,478,964	$347,904,017
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$68,071,259	$75,755,492	$128,264,419
Difference (f) = (e)-(d)	**-$116,565,015**	**-$129,723,472**	**-$219,639,598**

We received no public comments related to the burden estimates for submission of quality performance category data using the Medicare Part B claims collection type. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40858 through 40859) due to availability of updated data.

(4) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

This rule is not finalizing any new or revised collection of information requirements related to the MIPS CQM or QCDR collection types. However, we are making adjustments to our currently approved burden estimates based on more recent data. The requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 78, 79, and 80, and based on 2018 MIPS performance period data, we assume that 391,430 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. Of these, we expect 100,269 clinicians, as shown in Table 79, will submit as individuals and 10,949 groups and virtual groups, as shown in Table 80, are expected to submit on behalf of the remaining 291,161 clinicians. This is a decrease of 5,770 individuals and an increase of 397 groups from the CY 2020 PFS proposed rule's estimates of 106,039 individuals and 10,552 groups due to availability of more recent data (84 FR 40860). As previously stated, we assume clinicians in other practices (not small practices) who meet all of the following criteria will submit via the MIPS CQM collection type for the 2020 MIPS performance period because the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data: (1) Scored as individuals; (2) not facility-based; and (3) submitted quality data only via the Medicare Part B claims collection type in the 2018 MIPS performance period. As a result of this assumption and our use of more recent data, this rule is finalizing to adjust the number of QCDR and MIPS CQM respondents from 81,981 to 111,218 (an increase of 29,237). Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS collection requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data total 9.083 hours at $872.37 per individual clinician or group. This consists of 3 hours at $90.02/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $109.36/hr for a practice administrator, 1 hour at $90.02/hr for a computer systems analyst, 1 hour at $45.24/hr for a LPN/medical assistant, 1 hour at $38.00/hr for a billing clerk, and 1 hour at $202.86/hr for a clinician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) per clinician or group (respondent) for a cost of $7.50 (0.083 hr × $90.02/hr for a computer systems analyst).

In aggregate, we estimate an annual burden of 1,010,193 hours (9.083 hr/response × 111,218 groups plus clinicians submitting as individuals) at a cost of $97,023,431 (111,218 responses × $872.37/response). Based on these assumptions, we have estimated in Table 84 the burden for these submissions.

TABLE 84: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM/QCDR Collection Type

	Burden Estimate
# of clinicians submitting as individuals (a)	100,269
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	10,949
# of Respondents (groups plus clinicians submitting as individuals) (c)=(a)+(b)	111,218
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Practice Administrator Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Clinician Review Measure Specifications (i)	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k)= (d)+(e)+(f)+(g)+(h)+(i)+(j)	9.083
Total Annual Hours (l) = (c)*(k)	**1,010,193**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $90.02/hr) (m)	$270.06
Cost to Review Measure Specifications (@ practice administrator's labor rate of $109.36/hr) (n)	$218.72
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $90.02/hr) (o)	$90.02
Cost LPN Review Measure Specifications (@ LPN's labor rate of $45.24/hr) (p)	$45.24
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $38.00/hr) (q)	$38.00
Cost Clinician Review Measure Specifications (@ physician's labor rate of $202.86/hr) (r)	$202.86
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $90.02/hr) (s)	$7.50
Total Annual Cost Per Respondent (t) = (m)+(n)+(o)+(p)+(q)+(r)+(s)	$872.37
Total Annual Cost (u) = (c)*(t)	**$97,023,431**

As shown in Table 85, using the unchanged currently approved per respondent burden estimate, the increase in number of respondents from 81,981 to 111,218 results in a total increase of 265,560 hours (29,237 respondents × 9.083 hr/respondent) at a cost of $25,505,530 (29,237 respondents × $872.37/respondent).

TABLE 85: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM/QCDR Collection Type

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	744,633
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	1,010,193
Difference (c) = (b)-(a)	**+265,560**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$71,517,901
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$97,023,431
Difference (f) = (e)-(d)	**+$25,505,530**

We received no public comments related to the burden estimates for submission of quality performance category data using the MIPS CQM/QCDR collection type. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40860 through 40861) due to availability of updated data.

(5) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

This rule is not finalizing any new or revised collection of information requirements related to the eCQM

collection type. However, we are making adjustments to our currently approved burden estimates based on more recent data. The requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 78, 79, and 80, based on 2018 MIPS performance period data, we assume that 254,469 clinicians will elect to use the eCQM collection type; 38,935 clinicians are expected to submit eCQMs as individuals; and 4,398 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 208,921 clinicians. This rule finalizes to adjust the number of eCQM respondents from 51,861 to 43,333 (a decrease of 8,528) based on more recent data. This is a decrease of 8,520 individuals and an increase of 66 groups from the CY 2020 PFS proposed rule's estimates of 47,455 individuals and 4,332 groups due to availability of more recent data (84 FR 40861). We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their CEHRT and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to the CMS-designated clinical data warehouse.

We estimate that it will take no more than 2 hours at $90.02/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS submission. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $109.36/hr for a practice administrator, 1 hour at $202.86/hr for a clinician, 1 hour at $90.02/hr for a computer systems analyst, 1 hour at $45.24/hr for an LPN/medical assistant, and 1 hour at $38.00/hr for a billing clerk.

In aggregate we estimate an annual burden of 346,664 hours (8 hr × 43,333 groups and clinicians submitting as individuals) at a cost of $33,577,875 (43,333 responses × $774.88/response). Based on these assumptions, we have estimated in Table 86 the burden for these submissions.

TABLE 86: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

	Burden estimate
# of clinicians submitting as individuals (a)	38,935
# of Groups submitting via EHR on behalf of individual clinicians (b)	4,398
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	43,333
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Practice Administrator Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Clinicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j)=(d)+(e)+(f)+(g)+(h)+(i)	8
Total Annual Hours (k)=(c)*(j)	346,664
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $90.02/hr) (l)	$180.04
Cost to Review Measure Specifications (@ practice administrator's labor rate of $109.36/hr) (m)	$218.72
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $90.02/hr) (n)	$90.02
Cost to Review Measure Specifications (@ LPN's labor rate of $45.24/hr) (o)	$45.24
Cost to Review Measure Specifications (@ clerk's labor rate of $38.00/hr) (p)	$38.00
Cost to D21Review Measure Specifications (@ physician's labor rate of $202.86/hr) (q)	$202.86
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$774.88
Total Annual Cost (s) = (c)*(r)	**$33,577,875**

As shown in Table 87, using the unchanged currently approved per respondent burden estimate, the decrease in number of respondents from 51,861 to 43,333 results in a total difference of −68,224 hours (−8,528

respondents × 8 hr/respondent) at a cost of −$6,608,177 (−8,528 respondents × $774.88/respondent).

TABLE 87: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	414,888
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	346,664
Difference (c) = (b)-(a)	**-68,224**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$40,186,052
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$33,577,875
Difference (f) = (e)-(d)	**-$6,608,177**

We received no public comments related to the burden estimates for submission of quality performance category data using the eCQM collection type. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40861 through 40862) due to availability of updated data.

(6) Quality Data Submission via CMS Web Interface

This rule is not finalizing any new or revised collection of information requirements related to submission of quality data via the CMS Web Interface. However, we are making adjustments to our currently approved burden estimates based on more recent data. The requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We assume that 104 groups will submit quality data via the CMS Web Interface based on the number of groups who completed 100 percent of reporting quality data via the Web Interface in the 2018 MIPS performance period. This is a decrease of 182 groups from the currently approved number of 286 groups provided in the CY 2019 PFS final rule (83 FR 60007) due to receipt of more current data. We estimate that 46,473 clinicians will submit as part of groups via this method, a decrease of 92,758 from our currently approved estimate of 139,231 clinicians. This is a decrease of 69,869 individuals from the CY 2020 PFS proposed rule's estimate of 116,342 individuals due to availability of more recent data (84 FR 40862).

The burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is prepopulated in the CMS Web Interface. Our burden estimate for submission includes the time (61.67 hours) needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and submit the data (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and Part B beneficiaries). The patient data either can be manually entered, uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate, we estimate an annual burden of 6,414 hours (104 groups × 61.67 hr) at a cost of $577,359 (6,414 hr × $90.02/hr). Based on the assumptions discussed in this section, Table 88 summarizes the burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 88: Estimated Burden for Quality Data Submission via the CMS Web Interface

	Burden Estimate
# of Eligible Group Practices (a)	104
Total Annual Hours Per Group to Submit (b)	61.67
Total Annual Hours (c) = (a)*(b)	6,414
Cost Per Group to Report (@ computer systems analyst's labor rate of $90.02/hr.) (d)	$5,551.53
Total Annual Cost (e) = (a)*(d)	$577,359

As shown in Table 89, using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of −11,224 hours (−182 respondents × 61.67 hr) at −$1,010,379 (−11,224 hr × $90.02/hr).

TABLE 89: Change in Estimated Burden for Quality Data Submission via the CMS Web Interface

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	17,637
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	6,413
Difference (c) = (b)-(a)	**-11,224**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,587,739
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$577,359
Difference (f) = (e)-(d)	**-$1,010,379**

We received no public comments related to the burden estimates for submission of quality performance category data using the CMS Web Interface. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40862 through 40863) due to availability of updated data.

(7) Beneficiary Responses to CAHPS for MIPS Survey

This rule is not finalizing any new or revised collection of information requirements or burden related to the CAHPS for MIPS survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any MIPS survey vendor changes under that control number.

(8) Group Registration for CMS Web Interface

This rule is not finalizing any new or revised collection of information requirements related to the group registration for CMS Web Interface. However, we are adjusting our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an online registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 90, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $90.02/hr for a computer systems analyst (or their equivalent) to register the group.

In this rule, we are adjusting the number of respondents from 67 to 69 based on more recent data; an increase of 18 from our estimate of 51 in the CY 2020 PFS proposed rule (84 FR 40863). We assume that approximately 69 groups will elect to use the CMS Web Interface for the first time during the 2020 MIPS performance period based on the number of new registrations received during the CY 2019 registration period; an increase of 2 compared to the number of groups currently approved by OMB. As shown in Table 90, we estimate a burden of 17.25 hours (69 new registrations × 0.25 hr/registration) at a cost of $1,553 (17.255 hr × $90.02/hr).

TABLE 90: Estimated Burden for Group Registration for CMS Web Interface

	Burden Estimate
Number of New Groups Registering for CMS Web Interface (a)	69
Annual Hours Per Group (b)	0.25
Total Annual Hours (c) = (a)*(b)	**17.25**
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost (e) = (a)*(d)	**$1,553**

As shown in Table 91 using our unchanged currently approved per respondent burden estimates, the decrease in the number of groups registering to submit MIPS data via the CMS Web Interface results in an adjustment to the total time burden of 0.5 hours at a cost of $45 (−2 groups × 0.25 hr × $90.02/hr).

TABLE 91: Change in Estimated Burden for Group Registrations for the CMS Web Interface

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	16.75
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	17.25
Difference (c) = (b)-(a)	**+0.5**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,508
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$1,553
Difference (f) = (e)-(d)	**+$45**

We received no public comments related to the burden estimates for group registrations for the CMS Web Interface. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40863 through 40864) due to availability of updated data.

(9) Group Registration for CAHPS for MIPS Survey

This rule is not finalizing any new or revised collection of information requirements or burden related to the group registration for the CAHPS for MIPS Survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, are not making any MIPS survey vendor changes under that control number.

e. ICRs Regarding the Nomination of Quality Measures

The requirements and burden associated with this data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Quality measures are selected annually through a call for quality measures under consideration, with a final list of quality measures being published in the **Federal Register** by November 1 of each year. Under section 1848(q)(2)(D)(ii) of the Act, the Secretary must solicit a ''Call for Quality Measures'' each year. Specifically, the Secretary must request that eligible clinician organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of MIPS quality measures, as well as updates to the measures. Under section 1848(q)(2)(D)(ii) of the Act, eligible clinician organizations are professional organizations as defined by nationally recognized specialty boards of certification or equivalent certification boards.

As we described in the CY 2017 Quality Payment Program final rule (81 FR 77137), we will accept quality measures submissions at any time, but only measures submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual call for measures, which are further described at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html.*

To identify and submit a quality measure, eligible clinician organizations and other relevant stakeholders use a one-page online form that requests information on background, a gap analysis which includes evidence for the measure, reliability, validity, endorsement and a summary which includes how the proposed measure relates to the Quality Payment Program and the rationale for the measure. In addition, proposed measures must be accompanied by a completed Peer Review Journal Article form. As discussed in section III.K.3.c.(1)(d)(i) of this rule, we are finalizing that beginning with the 2020 Call for Measures process, MIPS quality measure stewards will be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards will also be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities. We believe this will require approximately 0.6 hours at $109.36/hr for a practice administrator and 0.4 hours at $202.86 for a clinician to research existing measures or activities and provide a rationale for the linkage to the new measure. We also estimate it will require 0.3 hours at $109.36/hr for a practice administrator to make a strategic decision to nominate and submit a measure and 0.2 hours at $202.86/hr for clinician review time. We recognize there is additional burden on respondents associated with development of a new quality measure beyond the 1.5 hour estimate (0.6 hr + 0.4 hr + 0.3 hr + 0.2 hr) which only accounts for the time required for recordkeeping, reporting, and third-party disclosures associated with the policy; but we believe this estimate to be reasonable to nominate and submit a measure. The 1.5 hour estimate also assumes that submitters will have the necessary information to complete the nomination form readily available, which we believe is a reasonable assumption. Additionally, some submitters familiar with the process or who are submitting multiple measures may require significantly less time, while other submitters may require more if the opposite is true. Representing an average across all respondents based on our review of the nomination process, the information required to complete the nomination form, and the criteria required to nominate the measure, we believe the total estimate of 1.5 hours per measure to be reasonable and appropriate.

As shown in Table 92, we estimate that 28 submissions will be received during the 2020 Call for Quality Measures based on the number of submissions received during the 2019 Call for Quality Measures process; a decrease of 112 compared to the number of submissions currently approved by OMB (140 submissions). This is an increase of 2 from the CY 2020 PFS proposed rule due to availability of more recent data (84 FR 40865). In keeping with the focus on clinicians as the primary source for recommending new quality measures, we are using

practice administrators and clinician time for our burden estimates.

Consistent with the CY 2017 Quality Payment Program final rule, we also estimate it will take 4 hours at $202.86/hr for a clinician (or equivalent) to complete the Peer Review Journal Article Form (81 FR 77153 through 77155). This assumes that measure information is available and testing is complete in order to have the necessary information to complete the form, which we believe is a reasonable assumption.

As shown in Table 92, in aggregate we estimate an annual burden of 154 hours (28 submissions × 5.5 hr/submission) at a cost of $28,884 {28 submissions × [(0.9 hr × $109.36/hr) + (4.6 hr × $202.86/hr)}.

TABLE 92: Estimated Burden for Call for Quality Measures

	Burden estimate
# of New Quality Measures Submitted for Consideration (a)	28
# of Hours Per Practice Administrator to Identify, Propose, and Link Measure (b)	0.9
# of Hours Per Clinician to Identify and Link Measure (c)	0.6
# of Hours Per Clinician to Complete Peer Review Article Form (d)	4.00
Annual Hours Per Response (e)= (b) + (c) + (d)	5.50
Total Annual Hours (f) = (a)*(e)	**154**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $109.36/hr.) (g)	$98.42
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ physician's labor rate of $202.86/hr.) (h)	$933.16
Total Annual Cost Per Respondent (i)=(g)+(h)	$1,031.58
Total Annual Cost (j)=(a)*(i)	**$28,884**

Independent of the decrease in the number of new quality measures submitted for consideration, the increase in burden per nominated measure results in a difference of 140 hours at a cost of $20,546 {140 submissions × [(0.6 hr × $109.36/hr) + (0.4 hr × $202.86/hr)]}. The decrease in the number of new quality measures submitted results in an adjustment of −616 hours at −$115,537 (−112 submissions × [(0.9 hr × $109.36/hr) + (4.6 hr × $202.86/hr)]). As shown in Table 93, in aggregate, the combine impact of these changes is −476 hours (140 − 616) at a cost of −$94,991 ($20,546 − $115,537).

TABLE 93: Change in Estimated Burden for Call for Quality Measures

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	630
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	154
Difference (c) = (b)-(a)	**-476**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$123,875
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$28,884
Difference (f) = (e)-(d)	**-$94,991**

We received no public comments related to the burden estimates for the Call for Quality Measures. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40864 through 40865) due to availability of updated data.

f. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the 2020 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. We have worked to further align the Promoting Interoperability performance category with other MIPS performance categories. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, which is not available for the quality performance category, we anticipate that individuals and groups will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. In the 2019 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category via a qualified registry or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type. The finalized policies discussed in sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this rule requiring qualified registries and QCDRs to be able to submit data for the quality, improvement activities, and Promoting Interoperability performance categories will alleviate this issue. Hence, the following burden estimates

show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

This rule is not finalizing any new or revised collection of information requirements related to the submission of reweighting applications for Promoting Interoperability and other performance categories. However, we are making adjustments to our currently approved burden estimates based on more recent data from the 2019 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability performance category in the following circumstances: Insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, clinicians who are in a small practice, and decertified EHR technology (81 FR 77240 through 77243 and 82 FR 53680 through 53686, respectively). In addition, in the CY 2018 Quality Payment Program final rule, we established that MIPS eligible clinicians and groups citing extreme and uncontrollable circumstances may also apply for a reweighting of the quality, cost, and/or improvement activities performance categories (82 FR 53783 through 53785). As discussed in section III.K.3.d.(2)(b)(ii)(A), we are finalizing, beginning with the 2018 MIPS performance period and 2020 MIPS payment year, to reweight the performance categories for a MIPS eligible clinician who we determine has data for a performance category that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents if we learn the relevant information prior to the beginning of the associated MIPS payment year. Because this is a new policy and we believe these occurrences are rare based on our experience, we are unable to estimate the number of clinicians, groups, or third party intermediaries that may contact us regarding a potential data issue. Similarly, the extent and source of documentation provided to us for each event may vary considerably. Therefore, we are not finalizing any changes to our currently approved burden estimates as a result of this policy. Respondents who apply for a reweighting for any of these performance categories have the option of applying for reweighting for the Promoting Interoperability performance category on the same online form. We assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

Table 94 summarizes the burden for clinicians to apply for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. Based on the number of reweighting applications received for the 2018 MIPS performance period, we assume 30,472 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship (including clinicians in small practices) or EHR decertification and an additional 148 respondents will submit a request only to reweight one or more of the quality, cost, or improvement activity performance categories, for a total of 30,620 reweighting applications submitted. This is an increase of 24,447 from our estimate of 6,025 in the CY 2020 PFS proposed rule due to availability of more recent data (84 FR 40866). A significant portion of this increase is due to a data issue CMS was made aware of and is specific to a single third-party intermediary. While we do not anticipate similar data issues to occur in each performance period, we do believe future similar incidents may occur and are electing to use this data without adjustment to reflect this belief. Of our total respondent estimate of 30,620, we estimate that 24,377 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. An additional 6,243 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship.

The application to request a reweighting to zero percent only for the Promoting Interoperability performance category is a short online form that requires identifying the type of hardship experienced or whether decertification of an EHR has occurred and a description of how the circumstances impair the clinician or group's ability to submit Promoting Interoperability data, as well as some proof of circumstances beyond the clinician's control. The application for reweighting of the quality, cost, Promoting Interoperability, and/or improvement activities performance categories due to extreme and uncontrollable circumstances requires the same information with the exception of there being only one option for the type of hardship experienced. We estimate it will take 0.25 hours at $90.02/hr for a computer system analyst to complete and submit the application. As shown in Table 94, we estimate an annual burden of 7,655 hours (30,620 applications × 0.25 hr/application) at a cost of $689,103 (7,655 hr × $90.02/hr).

TABLE 94: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

	Burden estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions (a)	24,377
# of Eligible Clinicians or Groups Applying Due to Significant Hardship for Small Practice (b)	6,243
Total Respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	30,620
Hours Per Applicant per application submission (d)	0.25
Total Annual Hours (e)=(a)*(c)	**7,655**
Labor Rate for a computer systems analyst (f)	$90.02/hr
Total Annual Cost (g)=(a)*(f)	**$689,103**

As shown in Table 95, using our unchanged currently approved per respondent burden estimate, the increased number of respondents results in a total adjustment of 6,145 hours (24,579 respondents × 0.25 hr/respondent) and $553,150 (24,579 respondents × $22.50/respondent).

TABLE 95: Change in Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	1,510
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	7,655
Difference (c) = (b)-(a)	**+6,145**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$135,953
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$689,103
Difference (f) = (e)-(d)	**+$553,150**

We received no public comments related to the burden estimates for reweighting applications for Promoting Interoperability and other performance categories. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40866 through 40867) due to availability of updated data.

(3) Submitting Promoting Interoperability Data

This rule is not finalizing any new or revised collection of information requirements related to the submission of Promoting Interoperability data. However, we are making adjustments to our currently approved burden estimates based on updated estimates of QPs and MIPS APMs for 2020 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

A variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264) and CY 2019 PFS final rule (83 FR 59822–59823), we established that eligible clinicians in MIPS APMs (including the Shared Savings Program) may report for the Promoting Interoperability performance category as an APM Entity group, individuals, or a group.

As shown in Table 96, based on data from the 2018 MIPS performance period, we estimate that a total of 74,281 respondents consisting of 59,865 individual MIPS eligible clinicians and 14,416 groups and virtual groups will submit Promoting Interoperability data; this is an adjustment to the number of respondents from 93,869 to 74,281 (a decrease of 19,588) based on more recent data. This is a decrease of 21,493 individuals and an increase of 1,911 groups from the CY 2020 PFS proposed rule's estimates of 81,358 individuals and 12,505 groups also due to availability of more recent data (84 FR 40868). In the CY 2017 and CY 2018 Quality Payment Program final rules, the CY 2019 PFS final rule, the CY 2020 PFS proposed rule, we were required to adjust our respondent estimates to account for MIPS eligible clinicians who we assumed would respond as participants in a virtual group. Because we are now able to base our respondent estimates on data from the 2018 MIPS performance period, which was the first performance period in which clinicians could submit as participants in a virtual group, we are no longer making the adjustment for virtual group participation.

Because our respondent estimates are based on the number of actual submissions received for the Promoting Interoperability performance category, it is not necessary to account for policies adopted in the CY 2017 Quality Payment Program final rule regarding reweighting, which state that if a clinician submits Promoting Interoperability data, they will be scored and the performance category will not be reweighted (81 FR 77238–77245). This approach is identical to the approach we used in the CY 2019 PFS final rule (83 FR 60013 through 60014);

however, we failed to state the distinction in that final rule that we no longer need to make modifications to our estimates due to the use of actual MIPS submission data. As established in the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2019 PFS final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of the Promoting Interoperability performance category to zero percent, including MIPS eligible clinicians that are hospital-based, ambulatory surgical center-based, non-patient facing clinicians, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists; occupational therapists; qualified speech-language pathologists or qualified audiologist; clinical psychologists; and registered dieticians or nutrition professionals (81 FR 77238 through 77245, 82 FR 53680 through 53687, and 83 FR 59819 through 59820, respectively). For the same reasons discussed above regarding our use of data reflecting the actual number of Promoting Interoperability data submissions received, these estimates already account for the reweighting policies in the CY 2017 and CY 2018 Quality Payment Program final rules, including exceptions for MIPS eligible clinicians who have experienced a significant hardship (including clinicians who are in small practices), as well as exceptions due to decertification of an EHR (81 FR 77240 through 77243 and 82 FR 53680 through 53686).

In section III.K.3.c.(4)(f)(iii) of this rule, we are finalizing to revise the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. We are finalizing that, beginning with the 2022 MIPS payment year, a hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period. We are also finalizing to revise § 414.1380(c)(2)(iii) to specify that for the Promoting Interoperability performance category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the finalized revised definition of a hospital-based MIPS eligible clinician or the definition of a non-patient facing MIPS eligible clinician as defined in § 414.1305. We believe these policies could result in a decrease in the number of data submissions for the Promoting Interoperability performance category, but we do not currently have the data necessary to determine how many groups would elect to forego submission. As additional information becomes available in future years, we will revisit the impact of this policy and adjust our burden estimates accordingly.

As discussed in section III.K.3.c.(4)(d)(i)(B) of this rule, we are finalizing to allow clinicians to satisfy the optional bonus Query of PDMP measure by submitting a ''yes/no'' attestation, rather than reporting a numerator and denominator. In the CY 2019 PFS final rule, we updated our burden assumptions from 3 hours to 2.67 hours to reflect the change from 5 base measures, 9 performance measures, and 4 bonus measures to the reporting of 4 base measures (83 FR 60013 through 60014). Due to a lack of data regarding the number of health care providers who would submit data for bonus Promoting Interoperability measures, we have consistently been unable to estimate burden related to the reporting of bonus measures and are therefore unable to account for any change in burden due to the proposed change to a ''yes/no'' attestation for the Query of PDMP measure. If we have better data in the future, we may reassess our burden assumptions and whether we can reasonably quantify the burden associated with the reporting of bonus measures.

We assume that MIPS eligible clinicians scored under the APM scoring standard, as described in section III.K.3.c.(5) of this rule, will continue to submit Promoting Interoperability data the same as in 2018. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA. However, in the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822–59823). Burden estimates for this final rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TINs as ACO participants. As we receive updated information which reflects the actual number of Promoting Interoperability data submissions submitted by Shared Savings Program ACO participants, we will update our burden estimates accordingly.

TABLE 96—ESTIMATED NUMBER OF RESPONDENTS TO SUBMIT PROMOTING INTEROPERABILITY PERFORMANCE DATA ON BEHALF OF CLINICIANS

	Number of respondents
Number of individual clinicians to submit Promoting Interoperability (a)	59,865
Number of groups to submit Promoting Interoperability (b)	14,416
Total Respondents in 2020 MIPS performance period (CY 2020 Final Rule) (c) = (a) + (b)	74,281
* Total Respondents in 2019 MIPS performance period (CY 2019 Final Rule) (d)	93,869
Difference (e) = (c) − (d)	−19,588

We estimate the time required for an individual or group to submit Promoting Interoperability data to be 2.67 hours. As previously discussed, we are finalizing changes to § 414.1400(a)(2) to state that beginning with the 2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all the MIPS performance categories identified in the regulation. Based on our review of 2019 qualified registries and QCDRs, we have determined that 70

percent and 72 percent of these vendors, respectively, are already able to submit data for these performance categories. For clinicians who currently utilize qualified registries or QCDRs that have not previously offered the ability to report Promoting Interoperability or improvement activity data, we believe this will result in a reduction of burden as it will simplify MIPS reporting. In order to estimate the impact on reporting burden, we would need to correlate the specific individual clinicians and groups who submitted quality performance category data via the MIPS CQM/QCDR collection type that are required to report data for both the quality and Promoting Interoperability performance categories with the specific qualified registries or QCDRs that are affected by this proposal. Currently, we do not have the necessary information to perform this correlation and are therefore unable to estimate the resulting impact on burden. If data becomes available in the future which enables us to perform this analysis, we will update our burden estimates at that time.

As shown in Table 97, the total burden estimate for submission of data on the specified Promoting Interoperability objectives and measures is estimated to be 198,083 hours (74,281 respondents × 2.67 incremental hours for a computer analyst's time above and beyond the clinician, practice manager, and computer system's analyst time required to submit quality data) at a cost of $17,831,402 (198,083 hr × $90.02/hr).

TABLE 97: Estimated Burden for Promoting Interoperability Performance Category Data Submission

	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	59,865
Number of groups to submit Promoting Interoperability (b)	14,416
Total (c) = (a) + (b)	74,281
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a)*(b)	**198,083**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (d)	$90.02/hr
Total Annual Cost (e) = (a)*(d)	**$17,831,402**

As shown in Table 98, using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of −52,235 hours (−19,588 respondents × 2.67 hr/respondent) at a cost of −$4,702,165 (−52,235 hr × $90.02/hr).

TABLE 98: Change in Estimated Burden for Promoting Interoperability Performance Category Data Submission

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	250,317
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	198,083
Difference (c) = (b)-(a)	**-52,235**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$22,533,566
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$17,831,402
Difference (f) = (e)-(d)	**-$4,702,165**

We received no public comments related to the burden estimates for submission of data for the Promoting Interoperability performance category. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40867 through 40869) due to availability of updated data.

g. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule is not finalizing any new or revised collection of information requirements related to the nomination of Promoting Interoperability measures. However, we are making adjustment to our currently approved burden estimates based on data from the 2019 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Consistent with our requests for stakeholder input on quality measures and improvement activities, we also requested potential measures for the Promoting Interoperability performance category that measure patient outcomes, emphasize patient safety, support improvement activities and the quality performance category, and build on the advanced use of CEHRT using 2015 Edition standards and certification criteria. Promoting Interoperability measures may be submitted via the Call for Promoting Interoperability

Performance Category Measures Submission Form that includes the measure description, measure type (if applicable), reporting requirement, and CEHRT functionality used (if applicable). This rule does not propose any changes to that form.

We estimate 10 proposals will be submitted for new Promoting Interoperability measures, based on the number of proposals submitted during the CY 2019 nomination period. This is a decrease of 37 from the estimate currently approved by OMB (47 proposals) under the aforementioned control number and a decrease of 18 from the 28 proposals estimated in the CY 2020 PFS proposed rule due to availability of more recent data (84 FR 40869). We estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $109.36/hr for a practice administrator to make a strategic decision to nominate that activity and submit an activity to us via email and 0.2 hours at $202.86/hr for a clinician to review the nomination. As shown in Table 99, we estimate an annual burden of 5 hours (10 proposals × 0.5 hr/response) at a cost of $734 (10 × [(0.3 h × $109.36/hr) + (0.2 hr × $202.86/hr)].

TABLE 99: Estimated Burden for Call for Promoting Interoperability Measures

	Burden Estimate
# of Promoting Interoperability Measure Nominations (a)	10
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
Annual Hours Per Respondent (d)= (b) + (c)	0.50
Total Annual Hours (e) = (a)*(d)	**5**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $109.36/hr) (f)	$32.81
Cost to Identify Improvement Measure (@ physician's labor rate of $202.86/hr) (g)	$40.57
Total Annual Cost Per Respondent (h)=(f)+(g)	$73.38
Total Annual Cost (i)=(a)*(h)	**$734**

As shown in Table 100, using our unchanged currently approved per respondent burden estimate, the decrease in the number of respondents results in an adjustment of −18.5 hours at a cost of −$2,715 (−37 respondents × 0.5 hr × $73.38 per respondent).

TABLE 100: Change in Estimated Burden for Call for Promoting Interoperability Measures

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	23.5
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	5
Difference (c) = (b)-(a)	**-18.5**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$3,449
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$734
Difference (f) = (e)-(d)	**-$2,715**

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We received no public comments related to the burden estimates for the Call for Promoting Interoperability measures. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40869 through 40870) due to availability of updated data.

h. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

This rule is not finalizing any new or revised collection of information requirements related to the submission of Improvement Activities data. However, we are making adjustments to our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section III.K.3.c.(3)(d)(iii) of this rule, after consideration of comments received, we are modifying our final policy to state that beginning with the 2020 MIPS performance period and for future years, each improvement activity for which groups and virtual groups submit a ''yes'' response must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and the NPIs must perform the same activity during a continuous 90-day period within the same performance year. Because eligible clinicians attest to improvement activities at the group level, there is no impact on reporting burden as a result of this policy.

As previously discussed, beginning with the 2023 MIPS payment year and for future years, we are finalizing to require QCDRs and qualified registries be able to submit data for three performance categories: Quality, improvement activities, and Promoting Interoperability; our discussion of burden for submitting Promoting Interoperability data in section VI.B.7.f.(3) noted our inability to account for the reduction in burden associated with the proposal. Consistent with our decision not to change our per respondent burden estimate to submit

Promoting Interoperability data, we are not changing our per respondent burden estimate to submit improvement activity data as a result of this policy.

Furthermore, as discussed in section III.K.3.c.(3)(e)(i) of this rule, we are finalizing to establish removal factors to consider when proposing to remove improvement activities from the Inventory. However, we do not believe this will affect reporting burden, because respondents will still be required to submit the same number of improvement activities and this policy will not require respondents to submit any additional information. We are also finalizing for the CY 2020 performance period and future years to: Add 2 new improvement activities, modify 7 existing improvement activities, and remove 15 existing improvement activities. Because MIPS eligible clinicians are still required to submit the same number of activities, we do not expect these proposals to affect our currently approved burden estimates. In addition, in order for an eligible clinician or group to receive credit for being a patient-centered medical home or comparable specialty practice, the eligible clinician or group must attest in the same manner as any other improvement activity. In In section III.K.3.c.(3)(d)(iii) of this final rule, we are also finalizing: (1) To modify the definition of rural area; (2) to update § 414.1380(b)(3)(ii)(A) and (C) remove the reference to the four listed accreditation organizations to be recognized as patient-centered medical homes and removing the reference to the specific accrediting organization for comparable specialty practices; and (3) to conclude and remove the CMS Study on Factors Associated with Reporting Quality Measures. Because these policies neither impact the number of respondents nor the time to submit data for the improvement activities performance category, we have made no associated changes to our burden estimate. We discuss the cost reduction associated with concluding the CMS Study on Factors Associated with Reporting Quality Measures in section VII.F.10.d of this final rule

While these finalized policies do not add additional reporting burden, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

The CY 2018 Quality Payment Program final rule provides: (1) That for activities that are performed for at least a continuous 90 days during the performance period, MIPS eligible clinicians must submit a ''yes'' response for activities within the Improvement Activities Inventory (82 FR 53651); (2) that the term ''recognized'' is accepted as equivalent to the term ''certified'' when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS (82 FR 53649); and (3) that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice (82 FR 53655).

In the CY 2017 Quality Payment Program final rule, we described how we determine MIPS APM scores (81 FR 77185). We compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77817 through 77831). If, based on our assessment, the MIPS APM does not receive the maximum improvement activities performance category score, then the APM Entity can submit additional improvement activities. We anticipate that MIPS APMs in the 2020 MIPS performance period will not need to submit additional improvement activities as the models will already meet the maximum improvement activities performance category score.

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group through direct, log in and upload submission types, and CMS Web Interface will also submit improvement activities data. In the 2019 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category through a MIPS CQM or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type, the finalized policies discussed in sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this rule requiring qualified registries and QCDRs to be able to submit data for all three of the MIPS performance categories identified in § 414.1400(a)(2) will help to alleviate this issue. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Our CY 2018 Quality Payment Program final rule burden estimates assumed that all APM Entities will receive the maximum CMS-assigned improvement activities score (82 FR 53921 through 53922).

As represented in Table 101, based on 2018 MIPS performance period data, we estimate that a total of 103,813 respondents consisting of 86,935 individual clinicians and 16,878 groups will submit improvement activities during the 2020 MIPS performance period; this is an adjustment to the number of respondents from 136,004 to 103,813 (a decrease of 32,191) based on more recent data. This is a decrease of 15,819 individuals and an increase of 1,117 groups from the estimates of 102,754 individuals and 15,761 groups provided in the CY 2020 PFS proposed rule due to availability of more recent data (84 FR 40871). In the CY 2017 and CY 2018 Quality Payment Program final rules, the CY 2019 PFS final rule, the CY 2020 PFS proposed rule, we were required to adjust our respondent estimates to account for MIPS eligible clinicians who we assumed would respond as participants in a virtual group. Because we are now able to base our respondent estimates on data from the 2018 MIPS performance period, which was the first performance period in which clinicians could submit as participants in a virtual group, we are no longer making the adjustment for virtual group participation. In addition, as previously discussed regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability performance categories, we have updated our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or members of an APM in the 2018 MIPS performance period but will be in the 2020 MIPS performance period, and will therefore not be required to submit improvement activities data.

Our burden estimates assume there will be no improvement activities burden for MIPS APM participants. We will assign the improvement activities performance category score at the APM Entity level. We also assume that the MIPS APM models for the 2020 MIPS performance period will qualify for the maximum improvement activities performance category score and, as

such, APM Entities will not submit any additional improvement activities.

TABLE 101: Estimated Numbers of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians

	Count
# of clinicians to participate in improvement activities data submission as individuals during the 2020 MIPS performance period (a)	86,935
# of Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (b)	16,878
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2020 MIPS performance period (CY 2020 Final Rule) (c) = (a) + (b)	103,813
*Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (CY 2019 Final Rule) (d)	136,004
Difference (e)=(c)-(d)	**-32,191**

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the CY 2019 PFS final rule, we estimate that the per response time required per individual or group is 5 minutes at $90.02/hr for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials (83 FR 60016).

As shown in Table 102, we estimate an annual burden of 8,651 hours (103,813 responses × 5 minutes/60) at a cost of $778,771 (8,651 hr × $90.02/hr).

TABLE 102: Estimated Burden for Improvement Activities Submission

	Burden Estimate
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (a)	103,813
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c) = (a)*(b)	**8,651**
Labor rate for a computer systems analyst to submit improvement activities (d)	$90.02/hr
Total Annual Cost (e) = (c)*(d)	**$778,771**

As shown in Table 103, using our unchanged currently approved per respondent burden estimate, the decrease in the number of respondents results in an adjustment of −2,683 hours (−32,191 responses × 5 minutes/60) at a cost of −$241,486 (−2,683 hr $90.02/hr).

TABLE 103: Change in Estimated Burden for Improvement Activities Submission

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	11,334
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	8,651
Difference (c) = (b)-(a)	**-2,683**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,020,257
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$778,771
Difference (f) = (e)-(d)	**-$241,486**

We received no public comments related to the burden estimates for submission of data for the Improvement Activities performance category. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40870 through 40872) due to availability of updated data.

i. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

This rule is not finalizing any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the nomination of improvement activities. However, we are making adjustments to our currently approved burden estimates based on data from the 2019 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule, for the 2018 and future MIPS performance periods, stakeholders were provided an opportunity to propose new activities formally via the Annual Call for Activities nomination form that was posted on the CMS website (82 FR 53657). The 2019 Annual Call for Activities lasted from February 1, 2019 through July 1, 2019, during which we received 31 nominations of new or modified activities which will be evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2020 Improvement Activities Inventory. Based on the number of improvement activity nominations received in the CY 2019 Annual Call for Activities, we estimate that we will receive 31 nominations for the 2020 Annual Call for Activities, which is a decrease of 94 from the 125 nominations currently approved by OMB and a decrease of 97 from the estimate of 128 provided in the CY 2020 PFS proposed rule (84 FR 40872).

We estimate 1.2 hours at $109.36/hr for a practice administrator or equivalent to make a strategic decision to nominate and submit that activity and 0.8 hours at $202.86/hr for a clinician's review. As shown in Table 104, we estimate an annual burden of 62 hours (31 nominations × 2 hr/nomination) at a cost of $9,099 (31 × [(1.2 hr × $109.36/hr) + (0.8 hr × $202.86/hr)]).

TABLE 104: Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
# of Nominations of New Improvement Activities (a)	31
# of Hours Per Practice Administrator to Identify and Propose Activity (b)	1.2
# of Hours Per Clinician to Identify Activity (c)	0.8
Annual Hours Per Respondent (d)= (b) + (c)	2
Total Annual Hours (e) = (a)*(d)	**62**
Cost to Identify and Submit Activity (@ practice administrator's labor rate of $109.36/hr) (f)	$131.23
Cost to Identify Improvement Activity (@ physician's labor rate of $202.86/hr) (g)	$162.29
Total Annual Cost Per Respondent (h)=(f)+(g)	$293.52
Total Annual Cost (i)=(a)*(h)	**$9,099**

As shown in Table 105, using our unchanged currently approved per respondent burden estimate, the decrease in the number of nominations results in an adjustment of −188 hours at a cost of −$27,591 {−94 activities × [(1.2 hr × $109.36/hr) + (0.8 hr × $202.86/hr)]}.

TABLE 105: Change in Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	250
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	62
Difference (c) = (b)-(a)	**-188**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$36,690
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$9,099
Difference (f) = (e)-(d)	**-$27,591**

We received no public comments related to the burden estimates for nomination of Improvement Activities. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40872 through 40873) due to availability of updated data.

j. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy, including for the 10 episode-based measures we are finalizing to include in the cost performance category as discussed in section III.K.3.c.(2)(b)(iii) of this rule. Moreover, the provisions of this final rule do not result in the need to add or revise or delete any claims data fields. Therefore, we are not finalizing any new or revised collection

of information requirements or burden for MIPS eligible clinicians resulting from the cost performance category.

k. Quality Payment Program ICRs Regarding Partial QP Elections (§§ 414.1310(b)(ii) and 414.1430)

This rule is not finalizing any new or revised collection of information requirements related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. However, we are making adjustments to our currently approved burden estimates based on updated projections for the 2020 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In section III.K.4.d.(2)(b), we are finalizing that, beginning for eligible clinicians who become Partial QPs in the 2021 MIPS performance period, Partial QP status will only apply to the TIN/NPI combination through which Partial QP status is attained. Any Partial QP election will only apply to TIN/NPI combination through which Partial QP status is attained so that an eligible clinician who is a Partial QP for only one TIN/NPI combination may still report under MIPS for other TIN/NPI combinations.

As shown in Table 106, based on our predictive QP analysis for the 2020 QP performance period, which accounts for the increase in QP and Partial QP thresholds, we estimate that 12 APM Entities and 2,010 eligible clinicians will make the election to participate as a Partial QP in MIPS representing approximately 15,500 Partial QPs, an increase of 1,941 from the 81 elections currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we estimate an annual burden of 505.5 hours (2,022 respondents × 0.25 hr/election) at a cost of $45,080 (505.5 hours × $90.02/hr).

TABLE 106: Estimated Burden for Partial QP Election

	Burden Estimate
# of respondents making Partial QP election (12 APM Entities, 2010 eligible clinicians) (a)	2,022
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a)*(b)	**505.5**
Labor rate for computer systems analyst (d)	$90.02/hr
Total Annual Cost (e) = (c)*(d)	**$45,505**

As shown in Table 107, using our unchanged currently approved per respondent burden estimate, the increase in the number of Partial QP elections results in an adjustment of 485.25 (1,941 elections × 0.25hr) at a cost of $43,682 (485.25 hr × $90.02/hr).

TABLE 107: Change in Estimated Burden for Partial QP Election

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	20.25
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	505.5
Difference (c) = (b)-(a)	**+485.25**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,823
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$45,505
Difference (f) = (e)-(d)	**+$43,682**

We received no public comments related to the burden estimates for Partial QP election. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40873 through 40874) due to availability of updated data.

l. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician Initiated Process (§ 414.1445)

As indicated below, the finalized requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer Initiated Process (§ 414.1445)

This rule is not finalizing any new or revised collection of information requirements related to the Payer-Initiated Process. However, we are making adjustments to our currently approved burden estimates based on updated projections for the 2020 MIPS performance period. As mentioned above, the adjusted burden will be submitted to OMB for approval.

As shown in Table 108, based on the actual number of requests received in the 2018 QP performance period, we estimate that in CY 2020 for the 2021 QP performance period 110 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (10 Medicaid payers, 50 Medicare Advantage Organizations, and 50 remaining other payers), a decrease of 105 from the 215 total requests currently approved by OMB under the

aforementioned control number. We estimate it will take 10 hours at $90.02/hr for a computer system analyst per arrangement submission. In aggregate, we estimate an annual burden of 1,100 hours (110 submissions × 10 hr/submission) at a cost of $99,022 (1,100 hr × $90.02/hr).

TABLE 108: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
# of other payer payment arrangements (10 Medicaid, 50 Medicare Advantage Organizations, 50 remaining other payers) (a)	110
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a)*(b)	**1,100**
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost (e) = (c)*(d)	**$99,022**

As shown in Table 109, using our unchanged currently approved per respondent burden estimate, the decrease in the number of payer-initiated requests from 215 to 110 results in an adjustment of −1,050 hours (−105 requests × 10 hr) at a cost of −$94,521 (−1,050 hr × $90.02/hr).

TABLE 109: Change in Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	2,150
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	1,100
Difference (c) = (b)-(a)	**-1,050**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$193,543
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$99,022
Difference (f) = (e)-(d)	**-$94,521**

We received no public comments related to the burden estimates for the Other Payer Advanced APM Identification Determinations: Payer-Initiated Process. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40874) due to availability of updated data.

(2) Eligible Clinician Initiated Process (§ 414.1445)

This rule is not finalizing any new or revised collection of information requirements or burden related to the Eligible-Clinician Initiated Process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the eligible clinician initiated process under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule is not finalizing any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option. However, we are making adjustments to our currently approved burden estimates based on updated projections for the 2020 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

The CY 2017 Quality Payment Program final rule provided that either APM Entities or individual eligible clinicians must submit by a date and in a manner determined by us: (1) Payment arrangement information necessary to assess whether each other payer arrangement is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; (2) for each payment arrangement, the amounts of payments for services furnished through the arrangement, the total payments from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed expected expenditures), and (3) the total number of patients furnished any service through the arrangement (81 FR 77480). The rule also specified that if we do not receive sufficient information to complete our evaluation of another payer arrangement and to make QP determinations for an eligible clinician using the All-Payer Combination Option, we will not assess the eligible clinicians under the All-Payer Combination Option (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we explained that in order for us to make QP determinations under the All-Payer Combination Option using either the payment

amount or patient count method, we will need to receive all of the payment amount and patient count information: (1) Attributable to the eligible clinician or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the QP performance period (82 FR 53885). We also finalized that eligible clinicians and APM Entities will not need to submit Medicare payment or patient information for QP determinations under the All-Payer Combination Option (82 FR 53885).

The CY 2018 Quality Payment Program final rule also noted that we will need this payment amount and patient count information for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 (82 FR 53885). We noted that the timing may be challenging for APM Entities or eligible clinicians to submit information for the August 31 snapshot date. If we receive information for either the March 31 or June 30 snapshots, but not the August 31 snapshot, we will use that information to make QP determinations under the All-Payer Combination Option. This payment amount and patient count information is to be submitted in a way that allows us to distinguish information from January 1 through March 31, January 1 through June 30, and January 1 through August 31 so that we can make QP determinations based on the two finalized snapshot dates (82 FR 30203 through 30204).

The CY 2018 Quality Payment Program final rule specified that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886).

In the CY 2019 PFS final rule, we finalized the addition of a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights to the TIN participate in a single (the same) APM Entity (83 FR 59936). This option will therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It will also be available to any other TIN for which all clinicians who have reassigned billing rights to the TIN are participating in a single APM Entity. To make QP determinations under the All-Payer Combination Option at the TIN level as finalized using either the payment amount or patient count method, we will need to receive, by December 1 of the calendar year that is 2 years to prior to the payment year, all of the payment amount and patient count information: (1) Attributable to the eligible clinician, TIN, or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician(s) during the QP performance period for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31.

As shown in Table 110, we assume that 20 APM Entities, 448 TINs, and 83 eligible clinicians will submit data for QP determinations under the All-Payer Combination Option in 2019, and increase of 242 from the 309 total submissions currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative, TIN representative, or eligible clinician 5 hours at $109.36/hr for a practice administrator to complete this submission. In aggregate, we estimate an annual burden of 2,755 hours (551 respondents × 5 hr) at a cost of $301,287 (2,755 hr × $109.36/hr).

TABLE 110: Estimated Burden for the Submission of Data for All-Payer QP Determinations

	Burden Estimate
# of APM Entities submitting data for All-Payer QP Determinations (a)	20
# of TINs submitting data for All-Payer QP Determinations (b)	448
# of eligible submitting data for All-Payer QP Determinations (c)	83
Hours Per respondent QP Determinations (d)	5
Total Hours (e)= [(a)*(d)]+[(b)*(d)]+[(c)*(d)]	**2,755**
Labor rate for a Practice Administrator (f)	$109.36/hr
Total Annual Cost (g) = (e)*(f)	**$301,287**

As shown in Table 111, using our unchanged currently approved per respondent burden estimate, the increase in the number of data submissions from 309 to 551 results in an adjustment of 1,210 hours (242 requests × 5 hr) at a cost of $132,326 (1,210 hr × $109.36/hr).

TABLE 111: Change in Estimated Burden for the Submission of Data for All-Payer QP Determinations

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	1,545
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	2,755
Difference (c) = (b)-(a)	**+1,210**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$168,961
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$301,287
Difference (f) = (e)-(d)	**+$132,326**

We received no public comments related to the burden estimates for the submission of data for All-Payer QP Determinations. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40875 through 40876) due to availability of updated data.

m. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule is not finalizing any new or revised collection of information requirements related to the election by voluntary participants to opt-out of public reporting on Physician Compare. However, we are making adjustment to our currently approved burden estimates based on data from the 2018 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We estimate that 10 percent of the total clinicians and groups who will voluntarily participate in MIPS will also elect not to participate in public reporting. This results in a total of 10,042 (0.10 × 100,415 voluntary MIPS participants) clinicians and groups, a decrease of 1,575 from the currently approved estimate of 11,617 and a decrease of 1,474 from the estimate of 11,516 respondents in the CY 2020 PFS proposed rule due to availability of more recent data (84 FR 40876) due to the availability of more recent data. Voluntary MIPS participants are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements set out in the CY 2019 PFS final rule but have elected to submit data to MIPS. As discussed in the RIA section of the CY 2019 PFS final rule, we estimate that 33 percent of clinicians that exceed one (1) of the low-volume criteria, but not all three (3), will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter (83 FR 60050).

In section III.K.3.h.(6) of this rule, we are finalizing to publicly report (1) an indicator if a MIPS eligible clinician is scored using facility-based measurement beginning with Year 3 (2019 performance information available for public reporting in late 2020) and (2) aggregate MIPS data beginning with Year 2 (2018 performance information available for public reporting in late 2019). We believe it is possible that the percentage of voluntary participants electing not to participate in public reporting may change as a result of these policies, we lack the ability to predict the behavior of clinicians' response to them. Table 112 shows that for these voluntary participants, we estimate it will take 0.25 hours at $90.02/hr for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 2,511 hours (10,042 requests × 0.25 hr/request) at a cost of $225,995 (2,511 hr × $90.02/hr).

TABLE 112: Estimated Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	10,042
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours (c) = (a)*(b)	**2,511**
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost (e) = (a)*(d)	**$225,995**

As shown in Table 113, using our unchanged currently approved per respondent burden estimate, the decrease in the number of opt outs by voluntary participants from 11,617 to 10,042 results in an adjustment of 393.75 hours (−1,575 requests × 0.25 hr) at a cost of −$35,445 (−393.75 hr × $90.02/hr).

TABLE 113: Change in Estimated Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	2,904.25
Total Annual Hours for Respondents in CY 2020 Final Rule (b)	2,511
Difference (c) = (b)-(a)	**-393.75**
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$261,441
Total Annual Cost for Respondents in CY 2020 Final Rule (e)	$225,995
Difference (f) = (e)-(d)	**-$35,445**

We received no public comments related to the burden estimates for voluntary participants to opt-out of performance data display on Physician Compare. The burden estimates have been updated from the CY 2020 PFS proposed rule (84 FR 40876 through 40877) due to availability of updated data.

n. Summary of Annual Quality Payment Program Burden Estimates

Table 114 summarizes this final rule's burden estimates for the Quality Payment Program. To understand the burden implications of the policies finalized in this rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2019 PFS final rule into the 2020 MIPS performance period. Our estimated baseline burden estimates reflect the availability of more accurate data to account for all potential respondents and submissions across all the performance categories, more accurately reflect the exclusion of QPs from all MIPS performance categories, and better estimate the number of third-parties likely to self-nominate as qualified registries and QCDRs, as well as the number of measures submitted per QCDR. The baseline burden estimate is 2,932,925 hours at a cost of $279,573,747. This baseline burden estimate is lower than the burden approved for information collection related to the CY 2019 PFS final rule due to updated data and assumptions. The difference of −276 hours and −$23,257 between this baseline estimate and the total burden shown in Tables 114 and 116 is the reduction in burden associated with impacts of finalized policies to require QCDRs to perform measure testing, partially offset by an increase in burden due to finalized policies requiring QCDRs to submit measure testing data and to require quality measures and QCDR measures be linked to existing cost measures, improvement activities, or MIPS Value Pathways, as feasible and applicable at the time of self-nomination.

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TABLE 114: Summary of Quality Payment Program Burden Estimates and Requirements

Requirement	Currently Approved Responses*	Finalized Responses	Change in Responses	Currently Approved Total Burden Hours*	Finalized Total Burden Hours	Change in Total Burden Hours
§ 414.1400 Registry self- nomination (see Tables 74 and 75)	150	153	3	450	459	9
§ 414.1400 QCDR self-nomination (see Tables 76 and 77)	200	76	-124	2,400	608	-1,792
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see Table 82)	257,260	94,846	-162,414	3,653,092	1,346,813	-2,306,279
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see Table 84)	81,981	111,218	29,237	744,633	1,010,193	265,560
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see Table 86)	51,861	43,333	-8,528	414,888	346,664	-68,224
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface (see Table 88)	286	104	-182	17,637.7	6,413.7	-11,224
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see Table 90)	67	69	2	16.75	17.25	0.5
(Quality Performance Category) Call for Quality Measures (see Table 92)	140	28	-112	630	154	-476
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see Table 94)	6,041	30,620	24,579	1,510	7,655	6,145
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see Table 97)	93,869	74,281	-19,588	250,317	198,083	-52,235
(Promoting Interoperability Performance Category) Call for Promoting Interoperability Measures (see Table 99)	47	10	-37	23.5	5	-18.5
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see Table 102)	136,004	103,813	-32,191	11,334	8,651	-2,683
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see Table 104)	125	31	-94	250	62	-188
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see Tables 106 and 107)	81	2,022	1,941	20.25	505.5	+485.25
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process (see Table 108)	215	110	-105	2,150	1,100	-1,050
§ 414.1440 Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option (see Table 110)	309	551	242	1,545	2,755	1,210
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants (see Table 112)	11,617	10,042	-1,575	2,904.25	2,511	-393.75
TOTAL	**640,253**	**471,307**	**-168,946**	**5,103,801**	**2,932,649**	**2,171,152**

*Currently approved under OMB control number 0938-1314 (CMS-10621).

Table 115 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this final rule. We have divided the reasons for our change in burden into those related to new policies and those related to adjustments in burden from continued Quality Payment Program Year 3 policies that reflect updated data and revised methods.

TABLE 115: Reasons for Change in Burden Compared to the Currently Approved CY 2019 Information Collection Burdens

Quality Payment Program Table	Changes in burden due to CY 2020 Final Rule policies	Adjustments in burden from continued CY 2019 Final Rule policies due to revised methods or updated data
Table 74: Qualified Registry Self-Nomination	None.	Increase in number of respondents due to availability of data from the 2019 self-nomination period.
Table 76: QCDR Self-Nomination	*Decrease in number of QCDR measures (from 9 to 2) submitted for approval due to finalized requirement for QCDRs to perform measure testing.* *Increase of 2 hours (1 hour per proposed measure) per QCDR self-nomination due to finalized policy to require QCDRs to link their QCDR measures as feasible to at least one cost measure, improvement activity, or MIPS Value Pathway.* *Increase of 1 hours (0.5 hour per proposed measure) per QCDR nomination due to finalized policy to require QCDRs to provide measure testing data at the time of self-nomination*	Decrease in number of respondents due to availability of data from the 2019 self-nomination period.
Table 82: Quality Performance Category Medicare Part B Claims Collection Type	None.	Decrease in number of respondents due to use of updated data from the 2018 MIPS performance period and data incorporating limitation on submission of quality data via Medicare Part B claims to small practices.
Table 84: Quality Performance Category QCDR/ MIPS CQM Collection Type	None.	Increase in number of respondents due to use of updated data from the 2018 MIPS performance period and data incorporating limitation on submission of quality data via Medicare Part B claims to small practices, and our assumption that affected clinicians will submit via the MIPS CQM collection type.
Table 86: Quality Performance Category eCQM Collection Type	None.	Decrease in number of respondents due to use of updated data from the 2018 MIPS performance period.
Table 88: Quality Performance Category CMS Web Interface	None.	Decrease in number of respondents due to use of updated data from the 2018 MIPS performance period.

Quality Payment Program Table	Changes in burden due to CY 2020 Final Rule policies	Adjustments in burden from continued CY 2019 Final Rule policies due to revised methods or updated data
Table 90: Registration for CMS Web Interface	None.	Increase in number of respondents due to updated data from the 2019 registration period.
Table 92: Call for Quality Measures	*Increase of 1 hour per measure due to finalized requirement to link nominated measures to existing cost measures or improvement activities.*	Decrease in number of measures submitted due to updated data from the 2019 Call for Quality Measures.
Table 95: Reweighting Applications for Promoting Interoperability and Other Performance Categories	None.	Increase in number of applications submitted due to updated data from the 2019 MIPS performance period.
Table 97: Promoting Interoperability Performance Category Data Submission	None.	Decrease in number of respondents due use of updated data from the 2018 MIPS performance period.
Table 99: Call for Promoting Interoperability Measures	None.	Decrease in number of measures submitted due to updated data from the 2019 Call for Promoting Interoperability Measures.
Table 102: Improvement Activities Submission	None.	Decrease in number of respondents due to use of updated data from the 2018 MIPS performance period.
Table 104: Nomination of Improvement Activities	None.	Decrease in number of activities nominated due to updated data from the 2019 Improvement Activity nomination period.
Table 106: Partial QP Election	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 108: Other Payer Advanced APM Identification: Other Payer Initiated Process	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 110: Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 112: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	None.	Decrease in the number of respondents due to use of updated data from the 2018 MIPS performance period.

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C. Summary of PRA-Related Requirements and Annual Burden Estimates

A summary of the PRA-related requirements and annual burden estimates is shown in Table 116.

TABLE 116: Annual Requirements and Burden

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number**	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*
§§ 403.902 and 403.904 ("Nature of Payment" Categories)***	0938-1237	400	400	5 - 30	5,895	44.92	264,804
		1,600	1,600	2 - 5	7,767	varies	410,941
§§ 403.902 and 403.904 (Standardizing Data Reporting for Covered Drugs, Devices, Biologicals, or Medical Supplies)***	0938-1237	450	450	20 - 100	24,840	44.92	1,115,813
		850	850	10 – 40	21,100	varies	1,013,740
		750	750	2 - 10	5,637	varies	311,384
Medicare Enrollment of Opioid Treatment Programs	0938-0685	633	633	2	1,900	37.50	262,523
Provider Agreement as Part of Enrollment Process	0938-0832-	633	633	0.167	53	varies	12,501
Quality Payment Program (See Subtotal Under Table 115)	0938-1314	343,152	-168,946	varies	-2,171,152	varies	-206,382,840
TOTAL		**384,432**	**-123,919**	**Varies**	**-1,722,544**	**Varies**	**-166,778,034**

* As it relates to the PRA, this rule will not impose any non-labor costs.

**OMB and CMS' PRA package ID numbers: OMB 0938-1237 (CMS-10495), OMB 0938-0685 (CMS-855B), and OMB 0938-1314 (CMS-10621).

***The burden for these changes to the Open Payments program represent one-time system changes.

D. Beneficiary Liability

Many policy changes could result in a change in beneficiary liability as it relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our public use file Impact on Payment for Selected Procedures available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/,* the CY 2019 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $109.92, which means that in CY 2019, a beneficiary would be responsible for 20 percent of this amount, or $21.98. Based on this final rule, using the CY 2020 CF, the CY 2020 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures public use file, is $110.43, which means that, in CY 2020, the final beneficiary coinsurance for this service would be $22.09.

VII. Regulatory Impact Analysis

A. Statement of Need

This final rule makes payment and policy changes under the Medicare PFS and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014 (PAMA), section 603 of the Bipartisan Budget Act of 2015, the Consolidated Appropriations Act of 2016, the Bipartisan Budget Act of 2018, and sections 2005 6063, and 6111 of the SUPPORT for Patients and Communities Act of 2018. This final rule also makes changes to payment policy and other related policies for Medicare Part B.

This final rule is necessary to make policy changes under Medicare fee-for-service. Therefore, we included a detailed Regulatory Impact Analysis (RIA) to assess all costs and benefits of available regulatory alternatives and explained the selection of these regulatory approaches that we believe adhere to statutory requirements and, to the extent feasible, maximize net benefits.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS provisions included in this final rule will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, *see* the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The PFS does not reimburse for services provided by rural hospitals; the PFS pays for physicians' services, which can be furnished by physicians and nonphysician practitioners (NPPs) in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017. We estimate the rule generates $0.61 million in annualized savings in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. This final rule is still considered an E.O. 13771 regulatory action due to potential unquantified cost. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

For the Quality Payment Program, we estimate that between 210,000 and 270,000 clinicians will become Qualifying APM Participants (QPs) and the total lump sum APM Incentive Payments will be approximately $535–685 million in the 2022 Quality Payment Program payment year. We estimate that approximately 880,000 clinicians will be MIPS eligible clinicians for the 2020 MIPS performance period. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments and positive MIPS payment adjustments ($433 million redistributed) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Up to an additional $500 million is also available for the 2022 MIPS payment year for additional positive MIPS payment adjustments for exceptional performance. Please refer to section VII.F.10 of this final rule for the full RIA of the Quality Payment Program.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule, we proposed a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2019 with payment rates for CY 2020 using CY 2018 Medicare utilization. The payment impacts in this final rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for CY 2015 and beyond. The update adjustment factor for CY 2020, as required by section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments.

To calculate the CY 2020 CF, we multiplied the product of the current year CF and the update adjustment factor by the budget neutrality adjustment described in the preceding paragraphs. We estimated the CY 2020 PFS CF to be 36.0896 which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act. We estimate the CY 2020 anesthesia CF to be 22.2774, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 117—CALCULATION OF THE CY 2020 PFS CONVERSION FACTOR

CY 2019 Conversion Factor		36.0391
Statutory Update Factor	0.00 percent (1.0000)	
CY 2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
CY 2020 Conversion Factor		36.0896

TABLE 118—CALCULATION OF THE CY 2020 ANESTHESIA CONVERSION FACTOR

CY 2019 National Average Anesthesia Conversion Factor		22.2730
Statutory Update Factor	0.00 percent (1.0000)	
CY 2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
CY 2020 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	−0.46 percent (0.9954)	
CY 2020 Conversion Factor		22.2016

Table 119 shows the payment impact on PFS services of the policies contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 119 (CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 119.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2018 utilization and CY 2019 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2020 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2020 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2020 impact on total allowed charges of the changes in the MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2020 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 119: CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$237	0%	0%	0%	0%
Anesthesiology	$2,002	0%	0%	0%	0%
Audiologist	$71	0%	1%	0%	1%
Cardiac Surgery	$281	-1%	-1%	0%	-2%
Cardiology	$6,618	0%	0%	0%	0%
Chiropractor	$756	0%	0%	-1%	-1%
Clinical Psychologist	$793	1%	2%	0%	3%
Clinical Social Worker	$787	0%	3%	0%	4%
Colon And Rectal Surgery	$163	0%	1%	0%	1%
Critical Care	$349	0%	0%	0%	0%
Dermatology	$3,550	0%	1%	-1%	0%
Diagnostic Testing Facility	$703	0%	-3%	0%	-3%
Emergency Medicine	$3,035	1%	0%	1%	1%
Endocrinology	$490	0%	0%	0%	0%
Family Practice	$6,056	0%	0%	0%	0%
Gastroenterology	$1,721	0%	0%	-1%	0%
General Practice	$410	0%	0%	0%	0%
General Surgery	$2,047	0%	0%	0%	0%
Geriatrics	$188	0%	0%	0%	0%
Hand Surgery	$226	0%	1%	0%	1%
Hematology/Oncology	$1,678	0%	0%	0%	0%
Independent Laboratory	$597	0%	1%	0%	1%
Infectious Disease	$643	0%	0%	0%	0%
Internal Medicine	$10,581	0%	0%	0%	0%
Interventional Pain Mgmt	$890	0%	1%	0%	1%
Interventional Radiology	$434	0%	-2%	0%	-1%
Multispecialty Clinic/Other Phys	$149	0%	0%	0%	0%
Nephrology	$2,176	0%	0%	0%	0%
Neurology	$1,512	-1%	-1%	0%	-2%
Neurosurgery	$807	0%	0%	-1%	0%
Nuclear Medicine	$50	0%	1%	0%	1%
Nurse Anes / Anes Asst	$1,297	0%	0%	0%	0%
Nurse Practitioner	$4,532	0%	0%	0%	0%
Obstetrics/Gynecology	$624	0%	1%	0%	1%
Ophthalmology	$5,413	-2%	-2%	0%	-4%
Optometry	$1,335	0%	-1%	0%	-2%
Oral/Maxillofacial Surgery	$72	0%	0%	-1%	-1%
Orthopedic Surgery	$3,750	0%	1%	0%	1%
Other	$35	0%	0%	0%	0%
Otolaryngology	$1,230	0%	0%	0%	0%
Pathology	$1,212	0%	0%	0%	0%
Pediatrics	$64	0%	0%	0%	0%
Physical Medicine	$1,117	0%	0%	0%	1%
Physical/Occupational Therapy	$4,273	0%	0%	0%	0%
Physician Assistant	$2,650	0%	0%	0%	0%
Plastic Surgery	$373	0%	0%	0%	0%
Podiatry	$2,017	0%	1%	0%	2%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Portable X-Ray Supplier	$96	0%	0%	0%	0%
Psychiatry	$1,134	0%	1%	0%	1%
Pulmonary Disease	$1,665	0%	0%	0%	0%
Radiation Oncology And Radiation Therapy Centers	$1,762	0%	0%	0%	0%
Radiology	$4,995	0%	0%	0%	0%
Rheumatology	$536	0%	0%	0%	0%
Thoracic Surgery	$355	-1%	0%	0%	-1%
Urology	$1,745	0%	1%	0%	1%
Vascular Surgery	$1,211	0%	-2%	0%	-2%
TOTAL	**$93,487**	**0%**	**0%**	**0%**	**0%**

* Column F may not equal the sum of columns C, D, and E due to rounding.

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2. CY 2020 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including clinical social workers, podiatry, urology, and obstetrics/gynecology reflect increases relative to other physician specialties. These increases can largely be attributed to finalized increases in value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee and CMS review, increased payments as a result of finalized updates to supply and equipment pricing, and the continuing implementation of the adjustment to indirect PE allocation for some office-based services.

The estimated impacts for several specialties, including ophthalmology and optometry, reflect decreases in payments relative to payment to other physician specialties as a result of revaluation of individual procedures reviewed by the AMA's relative value scale update committee (RUC) and CMS. The estimated impacts for other specialties, including vascular surgery, reflect decreased payments as a result of continuing implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased-in over several years. We also note that the estimated impact for the neurology specialty is decreasing as compared to the proposed impacts due to the decision to finalize contractor pricing for some of the new long term EEG monitoring services. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS. As a result, the estimated 1 percent increase for CY 2020 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 119), including comments received in response to the proposed rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in Table 119 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 119 displays the estimated CY 2020 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2020 PFS final rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

c. Estimated Impacts Related to Changes for Office/Outpatient E/M Services for CY 2021

Although we did not propose changes to E/M coding and payment for CY 2020, we proposed certain changes for CY 2021. In the proposed rule, we displayed an impact table that illustrated the specialty level impact associated with implementing the proposed changes to the office/outpatient E/M code set in CY 2020, rather than CY 2021. Table 120 reflects that we are finalizing as proposed.

We believe these estimates provide insight into the magnitude of potential changes for certain physician specialties but note that Table 120 does not take into account other changes to payment rates finalized for CY 2020 and should be considered for illustrative purposes only. Furthermore, as the CY 2021 impact of the revalued office/outpatient E/M code set will be inclusive of policies finalized in that year's rulemaking, we believe it would be premature to provide updated impacts for CY 2020. Table 120 illustrates the estimated specialty level impacts associated with finalizing the work values for the office/outpatient E/M codes, as well as the revalued HCPCS add-on G-code for primary care and certain types of specialty visits as proposed for CY 2020, exclusive of any other changes finalized for CY 2020.

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TABLE 120: Estimated Specialty Level Impacts of Finalized E/M Payment and Coding Policies

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*
Allergy/Immunology	$236	4%	3%	0%	7%
Anesthesiology	$1,993	-5%	-1%	0%	-7%
Audiologist	$70	-4%	-2%	0%	-6%
Cardiac Surgery	$279	-5%	-2%	-1%	-8%
Cardiology	$6,595	2%	1%	0%	3%
Chiropractor	$750	-5%	-3%	-1%	-9%
Clinical Psychologist	$787	-7%	0%	0%	-7%
Clinical Social Worker	$781	-7%	0%	0%	-6%
Colon And Rectal Surgery	$162	-3%	-1%	-1%	-4%
Critical Care	$346	-5%	-1%	0%	-6%
Dermatology	$3,541	0%	1%	-1%	-1%
Diagnostic Testing Facility	$697	-1%	-4%	0%	-4%
Emergency Medicine	$3,021	-6%	-2%	1%	-7%
Endocrinology	$488	11%	5%	1%	16%
Family Practice	$6,019	8%	4%	1%	12%
Gastroenterology	$1,713	-2%	-1%	-1%	-4%
General Practice	$405	5%	2%	0%	8%
General Surgery	$2,031	-3%	-1%	0%	-4%
Geriatrics	$187	2%	1%	0%	3%
Hand Surgery	$226	-1%	0%	0%	-1%
Hematology/Oncology	$1,673	8%	4%	1%	12%
Independent Laboratory	$592	-3%	-1%	0%	-4%
Infectious Disease	$640	-3%	-1%	0%	-3%
Internal Medicine	$10,507	2%	2%	0%	4%
Interventional Pain Mgmt	$885	4%	3%	1%	8%
Interventional Radiology	$432	-3%	-3%	0%	-6%
Multispecialty Clinic/Other Phys	$148	-2%	0%	0%	-2%
Nephrology	$2,164	-2%	0%	0%	-2%
Neurology	$1,503	2%	5%	0%	8%
Neurosurgery	$802	-3%	-1%	-2%	-6%
Nuclear Medicine	$50	-4%	0%	0%	-5%
Nurse Anes / Anes Asst	$1,291	-7%	-2%	0%	-9%
Nurse Practitioner	$4,503	5%	3%	0%	8%
Obstetrics/Gynecology	$620	4%	3%	0%	7%
Ophthalmology	$5,398	-4%	-5%	0%	-10%
Optometry	$1,325	-2%	-3%	0%	-5%
Oral/Maxillofacial Surgery	$71	-1%	-1%	-1%	-4%
Orthopedic Surgery	$3,734	-1%	0%	0%	-2%
Other	$34	-3%	-2%	0%	-5%
Otolaryngology	$1,225	3%	2%	0%	5%
Pathology	$1,203	-5%	-3%	-1%	-8%
Pediatrics	$62	3%	2%	0%	6%
Physical Medicine	$1,110	-2%	0%	0%	-2%
Physical/Occupational Therapy	$4,248	-4%	-3%	0%	-8%
Physician Assistant	$2,637	4%	2%	0%	7%
Plastic Surgery	$369	-3%	-1%	-1%	-5%
Podiatry	$1,998	0%	1%	0%	1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*
Portable X-Ray Supplier	$94	-1%	-3%	0%	-4%
Psychiatry	$1,120	4%	3%	0%	7%
Pulmonary Disease	$1,658	0%	1%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-2%	-2%	0%	-4%
Radiology	$4,971	-5%	-3%	0%	-8%
Rheumatology	$534	9%	5%	1%	15%
Thoracic Surgery	$352	-5%	-2%	-1%	-7%
Urology	$1,739	4%	4%	0%	8%
Vascular Surgery	$1,203	-2%	-3%	0%	-5%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

** Column F May Not Equal The Sum Of Columns C, D, And E Due To Rounding.*

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Overall, those specialties that bill higher level established patient visits, such as endocrinology or family practice, see the greatest increases as those codes were revalued higher relative to the rest of the office/outpatient E/M code set. Those specialties that see the greatest decreases are those that do not generally bill office/outpatient E/M visits. Other specialty level impacts are primarily driven by the extent to which those specialties bill using the office/outpatient E/M code set and the relative increases to the particular office/outpatient E/M codes predominantly billed by those specialties. We note that any potential coding changes and recommendations in overall valuation for new and existing codes between the CY 2020 rule and the CY 2021 final rule could impact the actual change in overall RVUs for office/outpatient visits relative to the rest of the PFS. Given the various factors that will be considered by the variety of stakeholders involved in the CPT and RUC processes, we do not believe we can estimate with any degree of certainty what the impact of potential changes might be. We also, note, however, that any changes in coding and payment for these services would be subject to notice and comment rulemaking.

As discussed elsewhere in this section of the final rule, we estimate this approach would lead to burden reduction for practitioners, while allowing a year of preparatory time and time for potential refinement over the next year as we take into account any feedback from stakeholders on these changes.

Comment: We received a number of comments on the impact analysis conducted to show the estimated specialty level impacts associated with implementing the proposed changes to the office/outpatient E/M code family for CY 2020, rather than CY 2021. Overall commenters requested that CMS provide more details as to how the impacts analysis was conducted, particularly the assumptions behind estimated utilization for HCPCS code GPC1X.

Response: For purposes of estimating the specialty level impacts we assumed that the following specialties would bill HCPCS code GPC1X with 100 percent of their office/outpatient E/M visit codes: Family practice, general practice, internal medicine, pediatrics, geriatrics, nurse practitioner, physician assistant, endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonary disease. We want to underscore that this was an assumption regarding which specialties are likely to furnish the types of medical care services that serve as the continuing focal point for all needed health care services or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition and is not meant to be prescriptive as to which specialties may bill for this service. As stated earlier, there are no specialty restrictions for billing HCPCS code GPC1X.

We encourage the public to submit additional information and recommendations regarding utilization for HCPCS code GPC1X prior to the February 10th deadline for submission of RUC and stakeholder valuation recommendations to be considered in CY 2021 rulemaking.

D. Effect of Changes Related to Telehealth

As discussed in section II.F. of this final rule, we proposed to add three new codes, HCPCS codes G2086, G2087, and G2088, to the list of Medicare telehealth services for CY 2020. Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the additions, we estimate there will only be a negligible impact on PFS expenditures from these additions. For example, for services already on the list, they are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall. The restrictions placed on Medicare telehealth by the statute limit the magnitude of utilization; however, we believe there is value in allowing physicians and patients the greatest flexibility when appropriate.

E. Effect of Changes Related to Physician Supervision for Physician Assistant (PA) Services

As discussed in section II.I of this final rule, we proposed to revise § 410.74(a)(2) such that the statutory physician supervision requirement for PA services at section 1861(s)(2)(K)(i) of the Act would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as required by state law in which the services are performed. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to

working with physicians in furnishing their services. This change would substantially align the regulation on physician supervision for PA services at § 410.74(a)(2) with our current regulations on physician collaboration for NP and CNS services at §§ 410.75(c)(3) and 410.76(c)(3). Our finalized policies are responsive to practitioner concerns that Medicare requirement for supervision of PA services may impose a more stringent standard than state laws governing physician supervision of PA services, and suggestions that the current regulatory definition of physician supervision as it applies to PAs could inappropriately restrict the practice of PAs in delivering their professional services to the Medicare population. While we expect that our finalized policies may result in increased administrative flexibility for PAs as they furnish services to patients, we cannot determine the specific impact our revised policies will have on practice business plans and demand for certain levels of clinicians though we expect that any emerging trends may be indicative of the current and expanded role of nonphysician practitioners as members of the medical team.

F. Other Provisions of the Regulation

1. Effect of Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section II.G of this final rule, section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act establishes a new Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs) for episodes of care beginning on or after January 1, 2020. The Substance Abuse and Mental Health Services Administration (SAMHSA) currently performs regulatory certification of OTPs. Currently, SAMHSA certifies about 1,700 OTPs. They are located predominately in urban areas, tend to be freestanding facilities, and provide a range of services, including medication-assisted treatment (MAT). The payor mix for OTPs currently includes Medicaid, private payors, TRICARE, as well as individual pay patients. The updated total estimated net Medicare and Medicaid impact, including FFS and Medicare Advantage, over 10 years is $1,484,000,000. We note that this estimate has increased compared to the estimate in the proposed rule, to reflect changes in the policies being finalized compared to the proposed policies, including the adoption of add-on codes describing intake activities and periodic assessments. In developing this estimate, it was assumed that the average treatment length would be 12 months in duration and the average rate per week in CY 2020 was assumed to be $220, which is a weighted average of the rates we are finalizing for the bundled payments for treatment with methadone, buprenorphine, and naltrexone and reflects the payment methodology that was finalized for the non-drug component, which sums the rates of similar services paid for under Medicare. It also includes payment for initial and periodic assessments that were added in this final rule. The initial assessment was assumed to be provided once at the beginning of treatment for patients new to the program. For the purpose of this estimate, it was assumed that periodic assessments would occur twice per year. These rates were updated annually by the Medicare Economic Index (MEI), based on our finalized policy.

We assumed that the impact in the first year would be reduced by 50 percent due to potential delays in provider enrollment and necessary investment by providers to transition to Medicare coding and billing systems. Additionally, any change to FFS benefits has an associated impact on payments to Medicare Advantage plans so an adjustment was made to reflect this impact, based on the projected distribution of spending in each year. The estimate also accounts for the impact on the program due to the change in the monthly Part B premium as a result of implementation of this new benefit, which we estimate to increase from approximately $0.09 (9 cents) in 2021 to $0.14 (14 cents) in 2029. The Part B enrollment and MEI assumptions were based on the President's Fiscal Year 2020 Budget baseline that was released in July of 2019. As with all estimates, and particularly those for new separately billable services, this outcome is highly uncertain because the available information on which to base estimates is limited and is not directly applicable to a new Medicare payment. The cost and utilization estimates are based on Medicare and Medicaid claims data for beneficiaries with OUD, together with statistics about the types of services typically furnished at OTPs.

It is difficult for us to predict how coverage of OTP services will specifically affect the market. We anticipate current OTPs may expand access to care for Medicare beneficiaries since they will be able to receive payment from Medicare for services furnished to beneficiaries when they previously were unable to do so. Coverage may also create financial incentives to establish new OTPs. However, since TRICARE, Medicaid, and some private payers already pay for OTP services, it is less clear whether the presence of Medicare payment rates will have any effect on current rates for OTP services or on new rates should additional private coverage be established.

2. Changes to the Ambulance Physician Certification Statement Requirement

This final rule will clarify the requirements at §§ 410.40 and 410.41 regarding the requirements for physician certification and non-physician certification statements and expand the list of staff members who can sign non-physician certification statements. While we believe that clarification of the regulatory provisions associated with physician certification and non-physician certification statements is needed and would be well received by stakeholders, we do not believe that these clarifications would have any substantive monetary or impact the amount of time needed to complete the certification statements. We believe the primary benefit of the clarification would be for providers and suppliers in preparing and submitting the original certification statements. It is feasible the clarification could result in fewer claims being denied. However, hypothetically, these denials are likely a small subset of the ambulance claim denials and those denied for technical PCS issues are likely appealed and overturned.

Moreover, we have examined the impact of expanding the list of individuals who may sign the non-physician certification statement. This added flexibility in accessing additional individuals to sign a non-physician certification statement would be needed only when the physician was unavailable. Thus, while we anticipate that some providers would use the increased flexibility, the precise impact is not calculable.

3. Medicare Ground Ambulance Data Collection System

As discussed in section III.B.2. of this final rule, section 50203(b) of the BBA of 2018 added a new paragraph (17) to section 1834(l) of the Act, which requires the Secretary to develop a data collection system to collect cost, revenue, utilization, and other information determined appropriate with respect to providers and suppliers of ground ambulance services. In

section III.B.4 through III.B.7. of this final rule, we outline the provisions that implement this section, including the data that will be collected through the data collection system, sampling methodology, requirements for reporting data, payment reductions that will apply to ground ambulance providers and suppliers that fail to sufficiently report data and that do not qualify for a hardship exemption, informal review process that will be available to ground ambulance providers and suppliers that are subject to a payment reduction, and our policies for making the data available to the public.

We estimate that ground ambulance providers and suppliers will need to engage in two primary activities with respect to these requirements, both of which will require them to incur cost and burden: Data collection and data reporting. The data collection activity includes: (1) Reviewing instructions to understand the data required for reporting; (2) accessing existing data systems and reports to obtain the required information; (3) obtaining required information from other entities where appropriate; and (4) if necessary, developing processes and systems to collect data that are not currently collected, but that they will be required to report under the data collection system. The data reporting activity includes entering the collected information in the Medicare Ground Ambulance Data Collection Instrument.

To estimate the data collection impact, we assumed that each ground ambulance organization that is selected to submit data for a year would take up to 20 hours to collect the required data, which would include 4 hours to review the instructions and 16 hours to collect the required data. These estimates were informed by our discussions with ambulance organizations during stakeholder engagements and through more in-depth interviews with nine ambulance organizations for the purpose of soliciting feedback on data collection instrument items as described in section III.B.3. and III.B.4. of this final rule. Most participants indicated that they would be able to provide some of the required information with an investment of 1–2 hours and complete information with additional hours to collect the missing data. Many participants indicated that they would need to reach out to other staff at the organization, at contracted organizations (such as billing companies), or at other entities (such as municipal government financial staff for government ambulance organizations) to collect required information that was not in the organization's accounting or billing systems. Some participants indicated that their organization would need to adjust data collection processes or collect new data over the course of a year to ensure that required data was available in the appropriate format prior to submission.

Actual data collection and reporting will vary depending on the mix of employees at sampled ambulance organizations, the staff with available time to dedicate to data collection and data reporting activities at each organization, the staff in different roles that already perform similar activities in each organization, and whether billing services are contracted out or conducted internally.

Because we expect that the staff (by category) that will contribute to data collection and reporting will be highly variable across ground ambulance organizations, we calculated a blended mean wage for the purposes of estimating burden. Table 121 lists the Standard Occupational Classification (SOC) categories contributing to the blended wage, the mean wage for each SOC specific to North American Industry Classification System (NAICS) industry code 621910 (Ambulance Services), and the relative contribution of each SOC to the blended mean. The source mean wage and employment data is from the Bureau of Labor Statistics May 2018 Occupational Employment Statistics data (available from *https://download.bls.gov/pub/time.series/oe/*) for the indicated SOC and NAICS codes, which was most recently available wage and employment data set. We assumed that financial clerks (SOC category 433000) would account for 25 percent of the total data collection and reporting effort, and that six other SOC categories would contribute to the remaining 75 percent (*see* Table 121).

TABLE 121: Estimated Mean Hourly Wages for Occupations Involved in Data Collection

Standard Occupational Classification Category	Mean Hourly Wage ($)	Weight (% Effort)*
Top Executives (111000)	51.49	17%
Other Management Occupations (119000)	39.23	12%
Business and Financial Operations Occupations (130000)	28.60	15%
Secretaries and Administrative Assistants (436010)	18.11	10%
Other Office and Administrative Support Workers (439000)	16.20	10%
Financial Clerks (433000)	18.51	25%
First-Line Supervisors of Office and Administrative Support Workers (431011)	27.92	10%
Blended Mean Hourly Wage	28.91	100%

*Note: Weights may not sum to 100 percent due to rounding. Source: Bureau of Labor Statistics Occupational Employment Statistics, May 2018, available from https://download.bls.gov/pub/time.series/oe/.

In addition, we calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage. Although we recognize that fringe benefits and overhead costs may vary significantly by employer, and that there are different accepted methods for estimating these costs, doubling the mean blended wage rate to estimate total cost is an accepted method to provide a reasonably accurate estimate. Therefore, assuming a mean blended wage of $28.91 for data collection, and assuming the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, we calculated a wage plus benefits estimate of $57.82 per hour of data collection. To calculate at the total data collection cost per sampled ground ambulance organization, we multiplied the time

required for data collection by the burdened hourly wage (20 hours * $57.82/hour) for a total of $1,156.

We discussed several sampling options in section III.B.5. of this final rule. We finalized our proposed sampling rate of 25 percent that would yield an expected 2,690 respondents (based on 2016 data) in the first sample, resulting in a total estimated data collection cost of $3,110,684 (2,690 respondents * $1,156 per respondent).

To estimate the cost of data reporting, we assumed it will require 3 hours to enter, review, and submit information into the proposed web-based data collection system. The estimate of 3 hours was also informed by interviews with nine ambulance organizations to solicit feedback on the data instrument items under consideration. We included time for staff to review the collected data before entering it into the data collection system. We also assumed that staff responsible for reporting the data would have the same blended hourly wage used to estimate data collection costs above ($28.91) as the staff that collected the data. Again, assuming the cost of overhead at 100 percent of the mean hourly wage, we calculated at a wage plus benefits estimate of $57.82. Therefore, we estimate a per-respondent cost for data submission of $173.46 (3 hours * $57.82/hour). To calculate the total cost for data reporting under a 25 percent sampling rate, we multiplied the number of ground ambulance organizations sampled annually by the time required for data entry times the total hourly wage estimate, for a total of $466,603 across all respondents (2,690 respondents * 3 hours * $57.82/hour).

Adding the total data collection and reporting costs yields a total annual impact for ground ambulance organizations of $3,577,287 ($3,110,684 for data collection [2,690 respondents * 20 hours * $57.82/hour] + $466,603 total cost for data submission [2,690 respondents * 3 hours * $57.82/hour]) with a 25 percent sampling rate. Our estimate of total annual impact would be lower at $1,430,649 ($1,244,042 for data collection [1,076 respondents * 20 hours * $57.82/hour] + $186,606 for data submission [1,076 respondents * 3 hours * $57.82/hour]) under a 10 percent sampling rate alternative and higher at $7,153,244 ($6,220,212 for data collection [5,379 respondents * 20 hours * $57.82/hour] + $933,032 for data submission [5,379 respondents * 3 hours * $57.82/hour]) under a 50 percent sampling rate. In all cases, the estimated cost of collecting and reporting data is $1,330 per organization sampled ($1,156 for data collection [20 hours * $57.82/hour] + $173.46 for data submission [3 hours * $57.82/hour]). The per-organization estimate reflects an average. Based on discussions with ambulance organizations to provide feedback on instrument items, we do not anticipate that larger or smaller ambulance organizations in terms of transport volume, costs, or revenue will face systematically more or less burden in data collection or reporting. While larger organizations generally have higher transport volumes, costs, and revenue, and more complex financial arrangements that may increase reporting burden, they also tend to have existing data collection and reporting processes and staff that will reduce the additional effort required to submit the required data. On the other hand, while smaller organizations have less data to collect and report, they may not have current processes in place to begin collecting some required data.

Comment: Two commenters disagreed with our estimate to complete the survey. One commenter stated for smaller organizations, compliance with the proposed cost reporting requirements will take considerably longer than the 20 hours over the course of 12 months estimated by CMS because a lot of the data being sought is not currently collected or sorted. The other commenter stated that the proposed estimate of 20 hours is not valid and should be 40 hours but would not include the time taken by others, such as the dispatcher or medical director, to collect the data. According to the commenter, the volunteer services do not collect a lot of data that is not directly needed for their operations and thus much of this will be new data.

Response: We understand that the length of time it will take to complete the data collection will vary considerably, depending on numerous factors including the organizational structure of the ambulance organization, the existing accounting and cost reporting system, and the size and characteristics of the ambulance organization. For some, the amount of time required will be less than the estimate, and for others, it will be more. The estimate we provided is based on our experience in working with ambulance organizations during the development of the survey, and the time generally required by other programs with similar data collection requirements. We note that the data collection system was designed so that respondents only are required to answer the questions that are relevant for their organization, so for some organizations, the reporting requirements will also be less than for others.

b. Hardship Exemption Process

As discussed in section III.B.7.b. of this final rule, we proposed a process for ground ambulance organizations to request and for CMS to grant hardship exemptions from the 10 percent payment reduction. To request a hardship exemption, we proposed that a ground ambulance organization would be required to complete and submit a request form that we would make available on the Ambulances Services Center website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.*

We estimate that 25 percent of the total number of ground ambulance organizations will be selected each year as the representative sample to report the required information under the data collection system. That is, 25 percent out of the total 10,758 NPIs, or 2,690 ambulance providers and suppliers.

While we expect that few, if any, ground ambulance organizations will request a hardship exception, we do not have experience in collecting data from ground ambulance organizations that could be used to develop an estimate, so we based our estimate on the total number of organizations being surveyed. As a result, we estimated that a total of 2,690 ground ambulance organizations would apply for a hardship exemption, and that it would take 15 minutes for each of these ground ambulance organizations 15 minutes to complete and submit the request form.

We assumed for purposes of this estimate that the mix of staff responsible for completing this form would have the same blended hourly wage used to estimate the data collection and data reporting costs. We also calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, as we did above. As a result, we estimated that the total cost burden associated with the completion and submission of the hardship exemption request form would be approximately $38,884.

We did not receive any comments on our estimate to complete the hardship exemption form. As we discussed in section III.B.7.b. of this final rule, we are finalizing our proposed process for hardship exemptions.

c. Informal Review Process

As discussed in section III.B.7.c. of this final rule, we proposed a process for a ground ambulance organization to seek an informal review of our determination that it is subject to the 10 percent reduction.

We estimate that a collection of information burden of 15 minutes for a

ground ambulance organization that is requesting an informal review to gather the requested information and send an email to our AMBULANCEODF mailbox.

We used the total number of ambulance organizations that will be surveyed each year to develop our estimates and estimated a total burden of 40,350 minutes (15 × 2,690) or 672.5 hours for 2,690 ground ambulance organizations to complete this process. Taking into account the same blended mean hourly wage and fringe benefits as we did for our other estimates, we estimated that the total for all sampled ground ambulance organizations to gather the requested information and submit the form would be approximately $38,884.

We did not receive any comments on our estimate to collect and submit the information for an informal review. As we discussed in section III.B.7.c. of this final rule, we are finalizing our proposed process to request an informal review.

4. Intensive Cardiac Rehabilitation (ICR)

As discussed in section III.C. of this final rule, we are adding stable, chronic heart failure (CHF) (defined as patient with left ventricular ejection fraction of 35 percent or less and NYHA class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks) to the list of covered conditions for ICR, as well as, the ability for use to use the NCD process to add additional covered conditions for ICR. Heart failure impacts approximately 5.7 million adults, and approximately 80 percent of individuals over age 65 have heart failure. (The majority (86 percent) of Medicare beneficiaries are over age 65.) We estimate 4,560,000 beneficiaries over age 65 have heart failure.

The uptake by beneficiaries has historically been low for CR and ICR. From February 2014 to 2017, after stable CHF was added to the covered conditions for CR, only 439,888 claims were processed for this service with a diagnosis code of CHF. Less than 1 percent of beneficiaries with heart failure utilized CR. Given that the uptake of ICR has been even lower than CR, we expect the same trend (low uptake) for intensive cardiac rehabilitation due to the nature of these programs which entail rehabilitation through lifestyle modification. We conducted a claims analysis that examined claims prior to and after a 2014 NDC that added stable CHF to the list of covered conditions for CR. Prior to the implementation of stable CHF as a covered condition for CR, 1.8 percent of claims for CR included a diagnosis code for CHF. After implementation, 4.7 percent of claims for CR included a diagnosis code for CHF. Therefore, for ICR, which has historically been utilized much less than CR (for example, when all CR and ICR claims are combined, only 1 percent of the claims are for ICR), we anticipate there may be a similar slight percentage increase in claims for ICR for treatment of stable CHF. Assuming a 4.7 percent increase in ICR claims due to adding stable CHF as a covered condition, we estimate an increase of 3,378 claims annually. For 2019, the facility and non-facility prices for CR and ICR are the same, and the average price is $120.93. Therefore, based on our estimated increase in claims, at an average price of $120.93, the estimated total cost of adding stable, chronic heart failure to the list of covered conditions for ICR is estimated at $408,502 annually. From 2010–2017, the median number of ICR visits per calendar year was 18 visits per beneficiary. Therefore, based on our expected increase in the number of claims (3,378), the estimated number of beneficiaries covered would be 187. Based on these estimates, we estimate there will only be a negligible impact on Medicare expenditures by finalizing this rule.

Additionally, we do not anticipate providers currently offering ICR would need to obtain any specialized technology and equipment to treat ICR patients with stable CHF beyond what they would obtain for ICR patients seeking treatment for the existing six covered conditions.

With the finalization of this rule, we now cover the seven cardiac conditions that constitute the vast majority of cardiac conditions that CR and ICR can treat. Due to the breadth of the covered conditions, we do not anticipate the need to use the NCD process to add additional covered conditions to CR and ICR in the near future.

Lastly, while CR and ICR have low utilization at this point in time, an increase in the number of CR and/or ICR providers in underserved areas could result in an increase in utilization due to increased availability/proximity to services. However, we are not able to accurately quantify the number of entities that would seek approval as CR or ICR programs. Additionally, we acknowledge, that the expansion of coverage to ICR could generate attention around the importance of CR/ICR and may increase beneficiary utilization.

5. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

In the Medicaid Promoting Interoperability Program, to keep electronic clinical quality measure (eCQM) specifications current and minimize complexity, we proposed to align the eCQMs available for Medicaid EPs in 2020 with those available for MIPS eligible clinicians for the CY 2020 performance period. We are finalizing this proposal as proposed. We anticipate that this alignment will reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, as many EPs are expected to report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on those eCQMs for 2020. Not implementing this alignment could lead to increased burden because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program, if they opt to report on newly added eCQMs for MIPS. We expect that this policy will have only a minimal impact on states, by requiring minor adjustments to state systems for 2020 to maintain current eCQM lists and specifications. State expenditures to make any systems changes required as a result of this policy will be eligible for 90 percent Federal financial participation.

For 2020, we proposed to require that Medicaid EPs report on any six eCQMs that are relevant to the EP's scope of practice, including at least one outcome measure, or if no applicable outcome measure is available or relevant, at least one high priority measure, regardless of whether they report via attestation or electronically. This policy would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established in § 414.1335(a)(1). If no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, he or she could report on any six eCQMs that are relevant. We are finalizing this policy as proposed. This policy will be a continuation of our policy for 2019 and we believe it will not create new burden for EPs or states.

We also proposed that the 2020 eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program who have demonstrated meaningful use in a prior year would be a minimum of any continuous 274-day period within CY

2020. We proposed to shorten the reporting period from a full calendar year to enable states to take attestations for 2020 as early as October 1, 2020. We noted that we believe this would improve states' flexibility as they move toward the end of the Medicaid Promoting Interoperability Program and the December 31, 2021 statutory deadline to make incentive payments. We explained that we believed that this proposal would create no additional burden for EPs or health IT vendors, as Certified EHR Technology (CEHRT) should be able to run eCQM reports for any number of days and during any time period. The eCQM reporting period would be a minimum and EPs could continue to report on a full calendar year if they wish. As in previous years, we proposed that the 2020 eCQM reporting period for EPs attesting to meaningful use for the first time would be any continuous 90-day period within the calendar year.

After considering the comments we received on this proposal, we are finalizing a continuous 90-day eCQM reporting period for all Medicaid EPs in 2020, rather than requiring a minimum of any continuous 274-day period within CY 2020 for EPs in the Medicaid Promoting Interoperability Program who have demonstrated meaningful use in a prior year. The reporting period is a minimum, and we encourage EPs to report on a longer period if they are able to do so. As discussed above, at section III.D of this final rule, we believe that finalizing a 90-day eCQM reporting period for 2020, as recommended by commenters, instead of the 274-day eCQM reporting period we proposed, is more likely to reduce burden on EPs, health IT vendors, states, and other stakeholders, as compared to a full-year period or the 274-day eCQM reporting period we proposed.

Finally, we proposed to change Medicaid policy for 2021 related to EP Meaningful Use Objective 1, Measure 1 (Conduct or review a security risk analysis (SRA)). We proposed to allow Medicaid EPs to conduct an SRA at any time during CY 2021, even if the EP conducts the SRA after attesting to meaningful use of CEHRT to the state. A Medicaid EP who has not completed an SRA for CY 2021 by the time he or she attests to meaningful use of CEHRT for CY 2021 would be required to attest that he or she will complete the required SRA by December 31, 2021. Currently, this measure must be completed in the same calendar year as the EHR reporting period. This may occur before, during, or after the EHR reporting period, though if it occurs after the EHR reporting period it must occur before the provider attests to meaningful use of CEHRT or before the end of the calendar year, whichever comes first. In practice, this means that EPs do not attest to meaningful use of CEHRT before completing this measure. However, due to the changes we previously made to the EHR and eCQM reporting period timelines for CY 2021, all Medicaid EPs are expected to attest to meaningful use of CEHRT on or before October 31, 2021. Accordingly, if we did not propose to change the deadline for conducting the SRA, Medicaid EPs would no longer have the option of completing an SRA at the end of the calendar year, and would likely have to complete one well before December 2021. If an EP typically conducts the security risk analysis at the end of each year, this timeline could create burden for the EP, and may not be optimal for protecting information security, because it could disrupt the intervals between security risk analyses. We have also heard feedback from health care providers that SRAs are generally conducted for a whole clinic and the current requirement would create burden on non-EP health care providers in 2021. We are finalizing this change as proposed. As noted in the proposed rule, we believe this policy would prevent additional burden for both EPs and non-EP health care providers. We acknowledge that some EPs might experience increased burden due to the risk of recoupments from what we believe would likely be a small minority of EPs who fail to produce sufficient documentation for the SRA. However, we believe this potential additional burden is clearly outweighed by the reduced burden on what we anticipate would be the vast majority of Medicaid EPs that are afforded flexibility to conduct the SRA at any point in the calendar year that aligns with their operational needs.

As also discussed in the proposed rule, this policy could create burden for states, as they might have to adjust their pre-payment and post-payment verification plans and conduct more thorough audits for this meaningful use objective. However, states are already required to conduct adequate oversight of the Medicaid Promoting Interoperability Program, including routine tracking and verification of meaningful use attestations (*see* 42 CFR 495.318(b), 495.332(c), and 495.368), and we did not propose to change that requirement for 2021. We have established at 42 CFR 495.322(b) that 90 percent federal financial participation will be available for state administrative expenditures related to Medicaid Promoting Interoperability Program audits and appeals that are incurred on or before September 30, 2023.

6. Medicare Shared Savings Program

In section III.F.1.b. of this final rule, we summarize certain modifications to the quality measure set used to assess the quality performance of ACOs participating in the Shared Savings Program based on changes made to the CMS Web Interface measures under the Quality Payment Program in section III.I.3.b.(1). Specifically, (1) revisions to the numerator guidance for ACO–17—Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention and maintaining the measure as pay-for-reporting for performance years 2019; and (2) reverting ACO–43—Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) to pay-for-reporting for 2 years (2020 and 2021) to account for a substantive change in the measure.

The net result of these modifications to the Shared Savings Program quality measure set will be a measure set of 23 measures for performance year 2020. These changes will have no impact on the number of measures an ACO is required to report; therefore, there is no expected change in reporting burden for ACOs.

7. Open Payments

a. Expanding the Definition of ''Covered Recipient'' (§§ 403.902, 403.904, and 403.908)

Our initial estimate based on the available information is that there will be approximately $10 million dollar per year in increased burden to reporting entities and the new covered recipient groups for submitting, collecting, retaining, and reviewing data. This estimate is based on existing burden calculations. It assumes that there will be 734,000 new records (~7 percent increase) reported about 205,000 (~33 percent increase) covered recipients.

We also believe there will be costs to reporting entities for updating their systems and reporting processes. However, we are unable to estimate these costs because they will vary depending on the reporting entity's individual circumstances.

As explained in section IV.5. of this final rule, section 6111(c) of the SUPPORT Act states that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the changes to the definition of a covered recipient. Therefore, a detailed breakdown is not provided in that section. The above estimates

however, do provide a RIA of this provision.

b. Modification of the ''Nature of Payment'' Categories (§§ 403.902 and 403.904)

We anticipate minor additional costs for system updates associated with our provision to modify the ''nature of payment'' categories. As we indicated in section III.F. of this final rule, said provisions are intended to add clarity. They will not increase the amount of information to be reported. Data already reported to us may simply be reported in a different category. We proposed these changes only to be made prospectively and did *not* propose to have manufactures and GPOs to make changes to previously reported data. This provision would, generally speaking, allow reporting entities to better characterize the nature of a payment and would not constitute a new requirement. Hence, the expected impact is minimal.

c. Standardizing Data Reporting (§§ 403.902 and 403.904)

Approximately 850 entities (approximately 53 percent), have reported a transaction that will require the addition of a device identifier when this final rule is implemented. The total cost of the addition of this new data element cannot be estimated because it would depend on: (1) Whether the entity already tracks this data element and (2) the extent to which the entity would need to update their system to be able to report this data element.

8. OTP Enrollment and Revocation of Physician/Eligible Professional Enrollment for Abusive Part B Prescribing or Patient Harm

i. OTP Enrollment

As stated previously in this final rule, we proposed that OTP providers be required to not only enroll in Medicare, but also to: (1) Pay an application fee at the time of enrollment; and (2) submit a set of fingerprints for a national background check (via FBI Applicant Fingerprint Card FD–258) from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the OTP. The following is a discussion of the associated impacts we estimated in the proposed rule.

a. Application Fee

The application fees for each of the past 3 calendar years (CY) were or are $560 (CY 2017), $569, (CY 2018), and $586 (CY 2019). Consistent with § 424.518, the differing fee amounts were predicated on changes/increases in the Consumer Price Index (CPI) for all urban consumers (all items; United State city average, CPI–U) for the 12-month period ending on June 30 of the previous year. Although we could not predict future changes to the CPI, the fee amounts between 2017 and 2019 increased by an average of $13 per year. We believed this was a reasonable barometer with which to establish estimates (strictly for purposes of the proposed rule) of the fee amounts in the first 3 CYs of this rule (that is, 2020, 2021, and 2022). We thus projected a fee amount of $599 in 2020, $612 for 2021, and $625 for 2022.

Applying these prospective fee amounts to the number of projected applicants in the rule's first 3 years, we estimated a cost to enrollees of $1,058,433 (or 1,767 × $599) in the first year, $41,004 (or 67 × $612) in the second year, and $41,250 (or 66 × $625) in the third year.

b. Fingerprinting

Based on the experiences of the provider community to date, we estimated that it would take each owner (BLS: Top Executives) approximately 2 hours at $123.32/hr to obtain and submit fingerprints. (According to the most recent BLS wage data for May 2018, the mean hourly wage for the general category of ''Top Executives'' is $61.66 (see *http://www.bls.gov/oes/current/oes_nat.htm#43 0000*). With fringe benefits and overhead, the figure is $123.32.)

As mentioned in the preamble of this final rule, SAMHSA statistics indicate that there are currently about 1,677 active OTPs. Of these, approximately 1,585 have full certifications and 92 have provisional certifications.

Although we did not have specific data on the matter, we projected, for purposes of our burden estimates, a total of 1,500 direct or indirect ownership interests in OTP providers that would require the submission of fingerprints over the first 3 years. This 1,500 figure is less than the 1,900 projected applicants (discussed in the ICR section of this rule) in the first 3 years following the final rule's publication because some applicants may have non-profit business structures and, thus, would not have owners. Furthermore, our estimation of individual owners who would qualify to submit fingerprints was based on a sampling of similar provider types, including DMEPOS suppliers (high risk), MDPP suppliers (high risk), rural health clinics (limited risk) and others.

As noted in the preamble to this final rule, however, the only OTPs that will be assigned to the high-risk level of categorical screening (thus requiring the submission of fingerprints) will be those that were not fully and continuously certified by SAMHSA since October 23, 2018. We believe this group represents about one-quarter of all projected OTP applications. Using our previously mentioned per-year projections of the number of enrolling OTPs, we believe that there will be 442 high-risk level applications in the first year, 17 in the second year, and 17 in the third year. (This results in a total of 476 OTPs.) In addition, application of the one-quarter percentage to the above-mentioned universe of 1,500 ownership interests results in a revised figure of 375 (1,500 × 0.25).

Applying these new figures to the aforementioned per year breakdown of applicants, we estimate a first year burden of 698 hours at a cost of $86,077 (698/hr × $123.32/hr). We obtained the 698 hour estimate by first dividing 442 (the number of first-year applicants) by 476, resulting in a figure of 0.93. We then multiplied 0.93 by 375 (the number of ownership interests over the 3-year period) and thereafter by 2 hours.

Applying this same formula, we projected a second-year time estimate of 26 hours (or 0.035 × 375 owners × 2 hr) at a cost of $3,206 (26 hr × $123.32/hr), and a third-year estimate of 26 hours (or 0.035 × 375 applicants × 2 hr) at a cost of $3,206 (26 hr × $123.32/hr). In aggregate, we estimated a burden of 750 hours (698 hr + 26 hr + 26 hr) at a cost of $92,489 ($86,077 + $3,206 + $3,206). When annualized over the 3-year period, we estimated an annual burden of 250 hours (750 hours/3) at a cost of $30,830 ($92,489/3).

c. Conclusion

We received no comments on our proposed estimates regarding application fees and fingerprinting. We are therefore finalizing them, subject to the modification of our fingerprinting projections.

ii. Revocation of Physician/Eligible Professional Enrollment for Improper Part B Prescribing or Patient Harm

As previously discussed in the proposed rule and this final rule, we proposed the following:

- Under existing § 424.535(a)(14), CMS may revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part D drugs that:

(i) Is abusive, and/or represents a threat to the health and safety of Medicare beneficiaries; or

(ii) fails to meet Medicare requirements. We proposed to expand the scope of § 424.535(a)(14) to include Part B drugs.

• In new §§ 424.530(a)(15) and 424.535(a)(22), respectively, we proposed that CMS could deny or revoke a physician's or other eligible professional's enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.

Using our current average annual number of revocations for improper Part D prescribing as a barometer, we project that approximately 10 revocations per year will occur due to our expansion of § 424.535(a)(14) to include Part B drugs. Regarding our patient harm provision, we project approximately 5 revocations per year. This is based on our statements in section III.H of this final rule that we will exercise our authority under this provision only in significant and exceptional cases of patient harm. This results in an annual estimated total of 15 revocations for these two provisions. Based on our internal statistics concerning the average annual amount of provider payments, we project a per-revoked provider amount of $50,000. We therefore estimate our combined annual projected savings to the Trust Funds (specifically, monies that would not otherwise be paid to the revoked providers) concerning the abusive Part B prescribing and patient harm revocation provisions to be $750,000 (15 revocations X $50,000) annually. Over 10 years, this results in a total savings of $7.5 million.

9. Deferring to State Scope of Practice Requirements

a. Ambulatory Surgery Centers

Currently, there are approximately 5,800 Medicare-participating ASCs. We are finalizing our proposal with modification at § 416.42(a)(1) to clarify that there are two components to any pre-procedure evaluation and require that, immediately before surgery, a physician must examine the patient to evaluate the risk of the procedure to be performed, and a physician or anesthetist must examine the patient to evaluate the risk of anesthesia for that procedure. We are finalizing this change to reduce ASC compliance burden and provide for patient assessment and care continuity while maintaining patient safety and care. At § 416.42(a)(1)(ii), we will allow an anesthetist or a physician to perform the required pre-surgical anesthesia risk evaluation. We do not believe this modification to the proposed policy affects our estimates.

In total, ASCs provided about 6.4 million services in 2016. We assume that 30 percent of all procedures will utilize the services of a nurse anesthetist instead of a physician to meet this requirement, which reduces the average cost of the examination. We estimate the pre-surgical anesthesia evaluation to take 15 minutes to complete. We are assuming these estimates based on previous experience and conversations with stakeholders.

According to 2018 Bureau of Labor Statistics data, the hourly cost for a physician (including fringe benefits and overhead calculated at 100 percent of the mean hourly wage) is approximately $203 ($51 for 15 minute evaluation), and the hourly cost for a nurse anesthetist is approximately $168 ($42 for 15 minute evaluation). Assuming 1.92 million procedures annually, we can predict a savings of approximately $17.3 million (($51 − $42) × 1.92 million). We have used our best estimate as to the percentage of pre-surgical evaluations by anesthetists overall.

b. Hospice

We are revising § 418.106 to permit hospices to accept orders for drugs from attending physicians who are physician assistants. We do not believe that there are any associated financial impacts for hospices.

10. Changes Due to Updates to the Quality Payment Program

In section III.K. of this final rule, we included our policies for the Quality Payment Program. In this section of the final rule, we present the overall and incremental impacts to the number of expected QPs and associated APM Incentive Payments. In MIPS, we estimate the total MIPS eligible population and the payment impacts by practice size for the 2020 MIPS performance period based on various proposed policies to modify the MIPS final score and the proposed new performance threshold and additional performance threshold. For this RIA, we updated performance period and eligibility data to reflect information submitted in the 2018 MIPS performance period.

a. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

From 2019 through 2024, through the Medicare Option, eligible clinicians receiving a sufficient portion of Medicare Part B payments for covered professional services or seeing a sufficient number of Medicare patients through Advanced APMs as required to become QPs, for the applicable performance period, will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services furnished during the calendar year immediately preceding the payment year. In addition, beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs.

The APM Incentive Payment is separate from and in addition to the payment for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year are exempt from MIPS reporting requirements and payment adjustment. Eligible clinicians who do not become QPs, but meet a lower threshold to become Partial QPs for the year, may elect to report to MIPS and, if they elect to report, would then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment. For the 2020 QP Performance Period, we define Partial QPs to be eligible clinicians in Advanced APMs who collectively have at least 40 percent, but less than 50 percent, of their payments for Part B covered professional services through an APM Entity, or collectively furnish Part B covered professional services to at least 25 percent, but less than 35 percent, of their Medicare beneficiaries through an APM Entity. This MIPS payment adjustment may be positive, negative, or neutral. If an eligible clinician does not attain either QP or Partial QP status, and does not meet any another exemption category, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25

percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B PFS services in a payment year based on performance during a prior performance period. Although the statute establishes overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the fourth payment year (2022 payment year) of the Quality Payment Program.

In section III.K.4.e.(3)(c)(ii) of this final rule, we amended the marginal risk standard finalized in § 414.1420(d)(5) by amending paragraph (d)(5)(i) to provide that in event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of § 414.1420(d), and we retained the exceptions for large losses and small losses as described in that section. We do not yet have experience with QP and Partial QP Determinations under the All-Payer Combination Option, as the 2019 QP Performance Period is the first year in which eligible clinicians can become QPs or Partial QPs under the All-Payer Combination Option. To date, we have only determined a modest number of payment arrangements from non-Medicare payers that meet the Other Payer Advanced APM criteria. However, we expect this policy may increase the number of arrangements that may meet the Other Payer Advanced APM financial risk criterion.

Based on our analysis there are 21,000 providers within 5 percent of performance year 2020 QP thresholds in Advanced APMs, and therefore, could potentially benefit from participation in Other Payer Advanced APMs. Assuming a static marketplace, there are between 100–150 eligible clinicians that would benefit from the change in the marginal risk requirement at this time (that is, in 2020 QP Performance Period). This is because there are likely to be only a small number of eligible clinicians who both (1) participate in the payment arrangements we determined were not Other Payer Advanced APMs, but will become Other Payer Advanced APMs under the policy, and (2) have QP scores just below the QP threshold. While this number may grow in the future as payers adopt payment arrangements designed to reflect the change in the marginal risk requirement, we anticipate the incremental impact of this policy will have a small impact on the number of clinicians that meet the QP threshold and the total number of payment arrangements that are determined to be Other Payer Advanced APMs for the 2020 QP Performance Period.

Overall, we estimated that for the 2020 QP Performance Period between 210,000 and 270,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum APM incentive payment in Payment Year 2022 based on 5 percent of their Part B allowable charges for covered professional services in the preceding year. These allowable charges for QPs are estimated to be between approximately $10,700 million and $13,700 million in total for the 2020 performance year. The analysis for this final rule used the 2019 second snapshot participation file, and the 2019 third snapshot participation file for the MSSP Basic Level E and MSSP Enhanced models. We estimate that the total lump sum APM Incentive Payments will be approximately $535–685 million for the 2022 Quality Payment Program payment year.

In section VII.F.10.b. of this final rule, we projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2020 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2020 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2020 QP Performance Period:

- Next Generation ACO Model, Comprehensive Primary Care Plus (CPC+) Model;
- Comprehensive ESRD Care (CEC) Model (Two-Sided Risk Arrangement);
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative);
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Oncology Care Model (Two-Sided Risk Arrangements);
- Medicare ACO Track 1+ Model;
- Bundled Payments for Care Improvement Advanced;
- Maryland Total Cost of Care Model (Maryland Care Redesign Program; Maryland Primary Care Program); and
- Medicare Shared Savings Program (Track 2, Basic Track Level E, and the ENHANCED Track).

We used the APM Participant Lists and Affiliated Practitioner Lists, as applicable, (*see* 81 FR 77444 through 77445 for information on the APM Participant Lists and QP determinations) for the Predictive QP determination file for 2019 to estimate QPs, total Part B allowed charges for covered professional services, and the aggregate total of APM incentive payments for the 2020 QP Performance Period. We examined the extent to which Advanced APM participants would meet the QP Thresholds of having at least 50 percent of their Part B covered professional services or at least 35 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

We received the following comments on the APM estimates:

Comment: One commenter expressed concern that the RIA estimates similar totals for the number of QPs in performance year 2019 and performance year 2020, reflecting a relatively flat projected growth of QPs in 2020.

Response: In the CY 2020 PFS proposed rule (84 FR 40732), we estimated the number of QPs based on the best data at the time of publication. Our current analysis reflects the most recent participation data as of August 31, 2019 and as a result our projections indicate an increase in the number of QPs for PY2020.

As a result of the availability of more recent data, we have updated our calculations in this final rule and estimate that for the 2020 QP Performance Period between 210,000 and 270,000 eligible clinicians will become QPs.

b. Estimated Number of Clinicians Eligible for MIPS Eligibility

(1) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior to Applying the Low-Volume Threshold Exclusion

To estimate the number of MIPS eligible clinicians for the 2020 MIPS performance period in this final rule, our scoring model used a combination of the first determination period from the 2019 MIPS performance period (from October 1, 2017 to September 30, 2018) and data from the end of calendar year 2018 (from October 1, 2018 to December 31, 2018). The first determination period from the 2019 MIPS performance period eligibility file was selected as it includes several eligibility files changes that affect the Quality Payment Program moving forward. The rationale for including the data from the end of CY 2018 was to create a 15-month window for assigning

MIPS eligible clinicians as we finalized in the CY 2019 PFS final rule (83 FR 59727 through 59730). We included 1.6 million clinicians (*see* Table 122) who had PFS claims from October 1, 2017 to December 31, 2018. We excluded from our analysis individual clinicians who were affected by the automatic extreme and uncontrollable policy finalized for the 2018 MIPS performance period/2020 MIPS payment year in the CY 2019 PFS final rule (83 FR 59876) as we are unable to predict how these clinicians would perform in a year where there was no extreme and uncontrollable event.

Clinicians are ineligible for MIPS (and are excluded from MIPS payment adjustment) if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group. Therefore, we excluded these clinicians when calculating those clinicians eligible for MIPS. Due to policy changes the exclusion for participants in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) has been removed.

For the estimated MIPS eligible population for the 2022 MIPS payment year, we restricted our analysis to clinicians who are a physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); a physical therapist, occupational therapist, speech-language pathologist, audiologist, clinical psychologist, and registered dietitian or nutrition professional as finalized in the CY 2019 PFS final rule (83 FR 60076).

As noted previously, we excluded QPs from our scoring model since these clinicians are not MIPS eligible clinicians. To determine which clinicians in the initial population of 1.6 million should be excluded as QPs, we used the APM Participant List for the first snapshot date for the 2019 QP performance period, supplemented by the most recent 2018 performance period APM participation data for those clinicians not on the 2019 first snapshot list. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2020 QP performance period. We assumed that all Partial QPs would elect to participate in MIPS and included them in our scoring model and eligibility counts. The projected number of QPs excluded from our model is 163,200. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2020 Medicare QP Performance Period; hence, our model may underestimate or overestimate the fraction of clinicians and allowed charges for covered professional services that will remain subject to MIPS after the exclusions.

We also excluded newly enrolled Medicare clinicians from our model. To identify newly enrolled Medicare clinicians, we used the enrollment date from the 2018 Quality Payment Program performance period data.

(b) Assumptions Related to Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (that is, TIN/NPI) or group (that is, TIN or APM entity) levels based on how data are submitted or at the APM Entity level if the clinician is part of a MIPS APM Entity scored under the APM scoring standard. To determine who among those in the total initial population of 1.6 million is a MIPS APM participant, we used those who are APMs in the 2018 performance period as well as the additional clinicians in the first snapshot date of the 2019 QP performance period. To determine who is a member of a virtual group we used those who are in a virtual group for the 2018 performance period. If a MIPS eligible clinician is determined to not be scored as a MIPS APM or virtual group participant, then their reporting type, that is, group (TIN) or individual (TIN/NPI) is based on their reporting for the CY 2018 MIPS performance period. If no data are submitted by a clinician (TIN/NPI) or the clinician's group (TIN), and the TIN/NPI is not associated with an APM Entity or virtual group during the performance period, then the low-volume threshold is applied at the TIN/NPI level to PFS charges and beneficiary count for the 2019 first determination period. A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment. Our method of modeling opt-in participation is described later in this section.

Table 122 presents the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.6 million clinicians in the analysis of the 2020 MIPS performance period after using 2018 MIPS performance period data and applying the policies for the 2020 MIPS performance period.

For the purposes of modeling, we made assumptions on group reporting to apply the low-volume threshold. One extreme and unlikely assumption is that no practices elect group reporting, virtual group reporting, or participate in an APM and the low-volume threshold would always be applied at the individual level. Although we believe a scenario in which only these clinicians would participate as individuals is unlikely, this assumption is important because it quantifies the minimum number of MIPS eligible clinicians. For this final rule model, we estimate there were approximately 220,000 clinicians [132] who would be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. In Table 122, we identify clinicians under this assumption as having ''required eligibility.''

We anticipate that groups that submitted to MIPS as a group or registered as a virtual group for the CY 2018 MIPS performance period will continue to do so for the CY 2020 MIPS performance period. Using this group assumption and including those identified with MIPS APM entities in our scoring model, we identified 639,004 MIPS eligible clinicians. In Table 122, we identify these clinicians who do not meet the low-volume threshold individually but are anticipated to submit to MIPS as a group, virtual group or MIPS APM as having ''group eligibility.'' Using CY 2018 MIPS performance period data, we can identify group reporting through the submission of improvement activities, Promoting Interoperability, or quality performance category data.

To model the opt-in policy finalized in the CY 2019 PFS final rule (83 FR 59735), we assumed that 33 percent of the clinicians who exceed at least one but not all low-volume threshold criteria and submitted data to CY 2018 MIPS performance period would elect to opt-in to MIPS. We selected a random sample of 33 percent of clinicians without accounting for performance. We believe this assumption of 33 percent opt-in participation is reasonable because some clinicians may choose not to submit data due to performance, practice size, or resources or alternatively, some may submit data, but elect to be a voluntary reporter and not be subject to a MIPS payment

[132] The count of 224,082 MIPS eligible clinicians for required eligibility includes those who participated in MIPS (206,226 MIPS eligible clinicians), as well as those who did not participate (17,856 MIPS eligible clinicians).

adjustment based on their performance. This 33 percent participation assumption is identified in Table 122 as ''Opt-In eligibility''. In this final rule analysis, we estimate an additional 20,644 clinicians would be eligible through this policy for a total MIPS eligible population of approximately 880,000. The leads to an associated $69 billion allowed PFS charges estimated to be included in the 2020 MIPS performance period.

TABLE 122: Description of MIPS Eligibility Status for CY 2022 MIPS Payment Year Using the CY 2020 PFS Assumptions**

		CY 2020 PFS Final Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	201,708	$48,349
	Do not participate in MIPS	18,610	$4,147
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	639,004	$15,426
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	20,644	$1,019
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**879,966***	68,941
Not MIPS Eligible			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	380,352	$9,069
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	81,982	$444
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	265,982	$10,980
Total Number of Clinicians Not MIPS Eligible		728,316	20,493
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,608,282	89,434

* Estimated MIPS Eligible Population

** Table 122 does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 20,000 clinicians and $1,672 million in PFS allowed charges). It also does not include excluded eligible clinicians in CPC+ APMs who otherwise would have been MIPS eligible (approximately 765 clinicians and $36 million in PFS allowed charges).

*** Allowed charges estimated using 2017 and 2018 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

There are approximately 380,352 clinicians who are not MIPS eligible, but could be if their practice decides to participate or they elect to opt-in. We describe this group as ''Potentially MIPS eligible''. These clinicians would be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group and all clinicians that could elect to opt-into MIPS do elect to opt-in. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate that the MIPS eligible clinician population could be as high as 1.26 million clinicians.

Finally, there are some clinicians who would not be MIPS eligible either because they or their group are below the low-volume threshold on all three criteria (approximately 82,000) or because they are excluded for other reasons (approximately 266,000).

Since eligibility among many clinicians is contingent on submission to MIPS as a group, virtual group, APM participation or election to opt-in, we will not know the number of MIPS eligible clinicians until the submission period for the 2020 MIPS performance period is closed. For this impact analysis, we used the estimated population of 879,966 MIPS eligible clinicians described above.

c. Estimated Impacts on Payments to MIPS Eligible Clinicians

(1) Summary of Approach

In sections III.K.3.c., III.K.3.d. and III.K.3.e. of this final rule, we present several provisions which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VII.F.10.c.(2) of this RIA as we describe our methodology to estimate MIPS payments for the 2022 MIPS payment year. We note that many of the MIPS policies from the CY 2019 Quality Payment Program final rule were only defined for the 2019 MIPS performance period and 2021 MIPS payment year (including the performance threshold, the additional performance threshold, the policy for redistributing the weights of the performance categories, and many scoring policies for the quality performance category) which precludes us from developing a baseline for the 2020 MIPS performance period and 2022 MIPS payment year if there was no new regulatory action. Therefore, our impact analysis looks at the total effect of the finalized MIPS policies on the MIPS final score and payment adjustment for CY 2020 MIPS performance period/CY 2022 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, which is a value determined by their performance in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As discussed in section VII.F.10.c.(2) of this final rule, we generally used the most recently available data from the Quality Payment Program which is data submitted for the 2018 MIPS performance period.

The estimated payment impacts presented in this final rule reflect averages by practice size based on Medicare utilization. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues that clinicians earn would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System, that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2020 Quality Payment Program for this final rule, we generally used 2018 MIPS performance period data. Our scoring model includes the 879,966 estimated number of MIPS eligible clinicians as described in section VII.F.10.b.(1)(b) of this RIA.

To estimate the impact of MIPS on eligible clinicians, we generally used the 2018 MIPS performance period data, including data submitted for the quality, improvement activities, and Promoting Interoperability performance categories, CAHPS for MIPS and CAHPS for ACOs, the total per capita cost measure, Medicare Spending Per Beneficiary (MSPB) clinician measure and other data sets.[133] We calculated a hypothetical final score for the 2020 MIPS performance period/2022 MIPS payment year for each MIPS eligible clinician using score estimates described in this section for quality, cost, Promoting Interoperability, and improvement activities performance categories.

Starting with the 2018 performance period, certain groups could apply to be a virtual group and would be scored as a single group. For our model, we assumed that clinicians who participated as virtual groups for 2018 would continue to be a virtual group for the 2020 performance period.

[133] Data submitted to MIPS for the 2017 MIPS performance period data was used for the improvement score for the quality performance category. We also incorporated some additional data sources when available to represent more current data.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a similar methodology described in the CY 2019 PFS final rule (83 FR 60053 through 60054) with the following modifications that reflect the newly finalized policies for the 2020 MIPS performance period and improvement to our modeling methodology. As discussed in section III.K.3.c.(1)(c)(ii) of this final rule, we increased the data completeness requirement for the CY 2020 performance period from 60 percent to 70 percent. As discussed in section III. K.3.c.(1) of this final rule, we finalized a quality performance category weight of 45 percent for the 2020 MIPS performance period.

We also applied modifications that were previously finalized including the validation process that was finalized in the CY 2017 Quality Payment Program final rule (81 FR 77289 through 77291), applying the topped out scoring cap that was finalized (82 FR 53721 through 53727) to the measures subject to the scoring cap for the 2019 MIPS performance period, and the provisions in section III.K.3.d.(1)(b)(i)(C) of this final rule for benchmarks based on flat percentages to avoid potential inappropriate treatment.

Finally, our model applied the APM scoring standard policies finalized in the CY 2019 PFS final rule (83 FR 59754) as modified by the provisions in section III.K.3.c.(5)(c)(i)(B) of this final rule to MIPS eligible clinicians identified as being scored as a MIPS APM in the eligibility section VII.F.10.b.(1)(b) of this final rule. As described in section III.K.3.c.(5)(c)(i)(B) of this final rule, we will apply a minimum score of 50 percent, or an 'APM Quality Reporting Credit', under the MIPS quality performance category for certain APM entities participating in MIPS. In our model, this 'APM Quality Reporting Credit' was implemented for APM Entities that do not use Web Interface. As described in section III.K.3.c.(5)(c)(i)(A) of this final rule, we calculate an aggregated APM Entity quality performance category score from submitted MIPS data by the participants in an APM Entity not required to use Web Interface.

As described in section VII.F.10.b.(1)(b) of this final rule, we are using the APM Participant List for the first snapshot date for the 2019 QP performance period supplemented by the most recent 2018 performance period APM participation data for those clinicians not on the 2019 first snapshot list, using all available data to identify

who is an APM participant. For this analysis, the only MIPS reported measures available that are reported by a MIPS APM Entity would be the Web Interface measures and CAHPS for ACOs. In the case of MIPS APM entities associated with APMs that require participating entities to report Web Interface measures and CAHPS for ACOs, if the APM Entity existed in 2018, we calculated a score based on the Web Interface submission and CAHPS for ACOs from the 2018 performance period. If the APM Entity did not submit MIPS quality performance data for the 2018 performance period and was participating in the Shared Savings Program, we calculated an aggregate score based on individual submissions similar to how we estimate aggregate scores for MIPS APM entities that are not required to utilize the Web Interface. If the APM Entity is new for 2019 and is associated with an APM that requires participating entities to submit Web Interface measures and CAHPS for ACOs (and therefore did not have the ability to submit Web Interface measures for the 2018 performance period), and the participating clinician was associated with a different APM Entity in 2018 we used the score of the 2018 associated Entity. If that participating clinician was not associated with a different APM Entity in 2018 we used the median Web Interface score because we would anticipate the new APM Entities would report quality using the Web Interface in the future. For the MIPS APMs that do not utilize Web Interface only, we calculated an average quality performance category score based on group and individual submissions and then applied the APM Quality Reporting Credit policy to add 50 percent to the MIPS quality performance category score for APM Entities submitting to MIPS as discussed in section III.K.3.c.(5)(c)(i)(B) of this final rule. All quality performance category scores would be capped at 100 percent after receiving the 50 percent APM Quality Reporting Credit.

(b) Methodology To Estimate the Cost Performance Category Score

In section III.K.3.c.(2) of this final rule, we finalized a cost performance category weight of 15 percent for the 2020 MIPS performance period. In section III.K.3.c(2)(b)(iii) of this final rule, we added 10 episode-based measures to the cost performance category beginning with the 2020 performance period in addition to the 8 episode-based measures finalized in the CY 2019 PFS final rule (83 FR 59767). In section III.K.3.c.(2)(b)(v) of this rule, we included the revised total per capita cost and MSPB clinician measures.

We estimated the cost performance category score using all measures finalized in section III.K.3.c.(2)(b)(viii) of this final rule. The total per capita cost measure performance was estimated based on the revised measure using claims data from October 2016 through September 2017. The MSPB clinician measure performance was estimated based on the revised measure using claims data from January through December of 2017. For the episode-based measures, we used the specifications for the 8 episode-based measures finalized in the CY 2019 PFS final rule (83 FR 35902 through 35903), the specifications for the 10 new episode-based measures discussed in section III.K.3.c.(2)(b)(iii) of this final rule and claims data from January through December of 2017. A limitation of this cost data is that it does not overlap with the 2018 calendar year so we did not have cost measures for clinicians (TIN/NPIs) that newly bill in 2018. Cost measures are scored if the clinicians or groups met or exceed the case volume: 20 For the total per capita cost measure, 35 for MSPB clinician, 10 for procedural episode-based measures, and 20 for acute inpatient medical condition episode-based measures. The cost measures are calculated for both the TIN/NPI and the TIN, except for the lower gastrointestinal hemorrhage measure, which we discussed in section III.K.3.c.(2)(vi)(B) of this final rule to calculate only for groups. For clinicians participating as individuals, the TIN/NPI level score was used if available and if the minimum case volume was met. For clinicians participating as groups, the TIN level score was used, if available, and if the minimum case volume was met. For clinicians with no measures meeting the minimum case requirement, we did not estimate a score for the cost performance category, and the weight for the cost performance category was redistributed according to section III.K.3.c.(2) of this final rule. The raw cost measure scores were mapped to scores on the scale of 1–10, using benchmarks based on all measures that met the case minimum and if the group or clinician exceeded the low-volume threshold during the relevant performance period. For the episode-based cost measures, separate benchmarks were developed for TIN/NPI level scores and TIN level scores. For each clinician, a cost performance category score was calculated as the average of the measure scores available for the clinician.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

As finalized in the CY2019 PFS final rule (83 FR 59856), we determine the eligible clinician's MIPS cost and quality performance category score in facility-based measurement based on Hospital VBP Program Total Performance Score for eligible clinicians or groups who meet the eligibility criteria, which we designed to identify those who primarily furnish services within a hospital. We estimate the facility-based score using the scoring policies finalized in the CY2018 Quality Payment Program final rule (82 FR 53763). In section III.K.3.d.(1)(c) of this final rule, we finalized technical changes for clarity and those changes do not affect the facility-based policies.

We used data for the first determination period for the 2019 performance period to attribute clinicians and groups to hospitals and assign the specific Hospital VBP Program Total Performance Score. If a Hospital VBP Program Total Performance Score could not be assigned to a clinician, in instances in which the attributed facility does not participate in the Hospital VBP program or no facility could be attributed, that clinician was determined as not eligible for facility-based measurement and assumed to participate in MIPS via other methods. We are not requiring eligible clinicians to opt-in to facility-based measurement; it is possible that a MIPS eligible clinician or a group is automatically eligible for facility-based measurement, but they participate in MIPS as an individual or a group. In these cases, we used the higher combined quality and cost performance category score, as reflected in the final score, from facility-based scoring compared to the combined quality and cost performance category score from MIPS submission-based scoring.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimated the Promoting Interoperability performance category score using the methodology described in the CY 2019 PFS final rule (83 FR 60055) with the following modifications that reflect the new policies for the 2020 MIPS performance period.

In section III.K.3.c.(4)(d)(i)(B) of this final rule, we modified the Query of PDMP measure to a yes/no response. The Query of PDMP measure was not modeled because the measure was not available in the 2018 MIPS performance period submissions data.

In section III.K.3.c.(4)(f)(iii) of this final rule, we revised the definition of hospital-based MIPS eligible clinician to include groups and virtual groups. We also stated that a hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician. In section III.K.3.c.(4)(f)(iv) of this final rule, we discussed accounting for a group or virtual group that meets the definition of a non-patient facing MIPS eligible clinician such that the group or virtual group only has to meet a threshold of more than 75 percent. Also, as described in sections III.K.3.c.(4)(f)(iii) and III.K.3.c.(4)(f)(iv) of this final rule, we assigned a zero percent weight for the Promoting Interoperability performance category for groups defined as hospital-based and non-patient facing, and redistribute the points associated with the Promoting Interoperability performance category to another performance category or categories. Therefore, in our impact analysis model, a group was only assigned a zero percent weight for the Promoting Interoperability performance category and the points for Promoting Interoperability performance category was redistributed if: (1) All the TIN/NPIs were eligible for reweighting as established at § 414.1380(c)(2)(iii) for MIPS eligible clinicians submitting data as a group or virtual group, or 2) the group met the revised definition of a hospital-based MIPS eligible clinician as discussed in section III.K.3.c.(4)(f)(iii) of this final rule or the definition of a non-patient facing MIPS eligible clinician, as discussed in section III.K.3.c.(4)(f)(iv) of this final rule, as defined in § 414.1305. We also incorporated into our model the policy to continue automatic reweighting for NPs, PAs, CNSs and CRNAs, physical therapists, occupational therapist, speech-language pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals as described in sections III.K.3.c.(4)(f)(i) and III.K.3.c.(4)(f)(ii) of this final rule.

In our model, for the APM participants identified in section VII.F.10.b.(1).(b).of this final rule, we simulated MIPS APM Entity scores by using submitted Promoting Interoperability data by groups or individuals that we identified as being in a MIPS APM to calculate an APM Entity score.

All other policies for the Promoting Interoperability performance category described in section III.K.3.c.(4) of this final rule did not impact our modeling methodology for this performance category because either the data were not available in the 2018 MIPS performance period submissions data or the changes reflect the modeling strategy previously used and described in the CY 2019 PFS final rule (83 FR 60055). For example, since the Verify Opioid Treatment Agreement measure was not modeled in the CY 2019 PFS final rule (83 FR 60055) because the measure was not available in the 2017 MIPS performance period submissions data, the removal of this measure did not impact our methodology for this final rule.

This is the first iteration of the model where there are small practice hardship applications, therefore, we only reweighted small practices if they submitted an application and did not submit Promoting Interoperability performance category data.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

We modeled the improvement activities performance category score based on CY 2018 MIPS performance period data and APM participation identified in section VII.F.10.b.(1)(b) of this final rule. In section III.K.3.c.(3)(d)(iii) of this final rule, we increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent for the improvement activities performance category beginning with the CY 2020 performance year and future years. We did not incorporate this change into our model because we did not have the information to model this provision. For the APM participants identified in section VII.F.10.b.(1)(b) of this final rule, we assigned an improvement activity performance category score of 100 percent.

Clinicians and groups not participating in a MIPS APM were assigned their CY 2018 MIPS performance period improvement activities performance category score.

(f) Methodology To Estimate the Complex Patient Bonus

In section III.K.3.d.(2)(a) of this final rule, we continued the complex patient bonus for the 2020 MIPS performance period. Consistent with the policy to define complex patients as those with high medical risk or with dual eligibility, our scoring model used the complex patient bonus information calculated for the 2018 performance period data.

(g) Methodology To Estimate the Final Score

As discussed in sections III.K.3.c.(1)(b), III.K.3.c.(2)(a), and summarized in section III.K.3.d.(2)(b) of this final rule, our model assigns a final score for each TIN/NPI by multiplying each performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, and adding the complex patient bonus. After adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points equal to 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to section III.K.3.d.(2)(b)(iii) of this final rule.

(h) Methodology To Estimate the MIPS Payment Adjustment

As described in the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we applied a hierarchy to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available (for example if a clinician qualifies for a score for an APM entity and a group score, we select the APM entity score).

We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages and additional payment adjustment for exceptional performance (as finalized under § 414.1405), using a performance threshold of 45 points and the additional performance threshold of 85 points (as discussed in sections III.K.3.e.(2) and III.K.3.e.(3) of this final rule). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the paid amount for covered professional services furnished by the MIPS eligible clinician. We considered other performance thresholds which are discussed in section VII.F.2. of this RIA.

(3) Impact of Payments by Practice Size

Using the assumptions provided above, our model estimates that $433 million would be redistributed through budget neutrality and that $500 million would be distributed to MIPS eligible clinicians that meet or exceed the additional performance threshold. The model further estimates that the maximum positive payment adjustments are 6.2 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance.

Table 123 shows the impact of the payment adjustments by practice size and based on whether clinicians are expected to submit data to MIPS. We estimate that a smaller proportion of clinicians in small practices (1–15 clinicians) who participate in MIPS will receive a positive or neutral payment adjustment compared to larger sized practices. In aggregate, the cohort of clinicians in small practices participating in MIPS and who submit to MIPS receive a 1.0 percent increase in total paid amount, which is lower than the comparative payment increases received by the cohort of MIPS eligible clinicians in larger-sized practices. Table 123 also shows that 92.5 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. We want to highlight that we are using 2018 MIPS performance period submissions data for these calculations, and it is likely that there will be changes that we cannot account for at this time because the performance thresholds increased for the 2020 MIPS performance period to avoid a negative payment adjustment.

The combined impact of negative and positive adjustments and the additional positive adjustments for exceptional performance as a percent of paid amount among those that do not submit data to MIPS was not the maximum negative payment adjustment of 9 percent possible because these clinicians do not all receive a final score of zero. Indeed, some MIPS eligible clinicians that do not submit data to MIPS may receive final scores above zero through performance on the cost performance category, which utilizes administrative claims data and does not require separate data submission to MIPS. Among those who we estimate would not submit data to MIPS, 89 percent are in small practices (15,993 out of 18,017 clinicians who do not submit data). To address participation concerns, we have policies targeted towards small practices including technical assistance and special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs. We also note this participation data is generally based off participation for the 2018 performance period and that participation may change for the 2020 performance period.

TABLE 123: MIPS Estimated Payment Year 2022 Impact on Total Estimated Paid Amount by Participation Status and Practice Size*[a]

Practice Size*	Number of MIPS eligible clinicians	Percent MIPS Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent MIPS Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent MIPS Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount**
Among those submitting data* **					
1) 1-15	140,825	81.1%	36.2%	18.9%	1.0%
2) 16-24	43,304	87.4%	40.0%	12.6%	1.3%
3) 25-99	199,829	92.0%	40.7%	8.0%	1.4%
4) 100+	477,991	96.5%	50.3%	3.5%	1.8%
Overall	**861,949**	**92.5%**	**45.3%**	**7.5%**	**1.4%**
Among those not submitting data					
1) 1-15	15,993	0.0%	0.0%	100.0%	-8.6%
2) 16-24	663	0.0%	0.0%	100.0%	-8.6%
3) 25-99	904	0.0%	0.0%	100.0%	-8.8%
4) 100+	457	0.0%	0.0%	100.0%	-8.7%
Overall	**18,017**	**0.0%**	**0.0%**	**100.0%**	**-8.6%**

*Practice size is the total number of TIN/NPIs in a TIN.

** 2018 data used to estimate 2020 performance period payment adjustments. Payments estimated using 2018 dollars trended to 2022. The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.

***Includes facility-based clinicians whose quality data is submitted through hospital programs.

We received the following comments about our MIPS impact analysis:

Comment: One commenter raised concerns that scoring policies may inadvertently disadvantage smaller (but not small) groups and individual clinicians, and encouraged CMS to continue analyzing and addressing differences that are found.

Response: We agree on the importance of evaluating the impact of scoring policies that affect payment distributions. Table 123 analyzes the impact of payment redistribution by differing practice sizes. In our analysis, over 80 percent of clinicians in small practices (1–15 clinicians) that submit data to MIPS would receive a positive or neutral adjustment. The table also shows the results for practices of 16 to 25 clinicians.

After consideration of public comments, we have not updated our approach to the estimating the impact of the MIPS payments, however, we did update several data sources.

e. Potential Costs of Compliance With the Promoting Interoperability and Improvement Activities and Cost Performance Categories for Eligible Clinicians

(1) Potential Costs of Compliance With Promoting Interoperability Performance Category

In section III.K.3.c.(4)(d)(i)(B) of this final rule, we allow clinicians and groups to satisfy the optional bonus Query of PDMP measure by submitting a ''yes/no'' attestation, rather than reporting a numerator and denominator. As discussed in the Collection of Information section of this final rule, we are not changing our burden assumptions to account for this policy due to a lack of information regarding the number of clinicians reporting bonus measures combined with our currently approved burden estimates being based only on the reporting of required measures. However, we do believe that for clinicians or groups who report this measure, there will be a reduction in reporting burden compared to what would have been required to submit the measure without this change related to the elimination of the need to perform calculations prior to submitting a numerator and denominator. As data availability allows, we will reassess the inclusion of this burden in the Collection of Information in the future.

In sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this rule, beginning with the 2021 performance period and for future years, we require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In the Collection of Information section, we discussed the potential burden reduction associated with simplifying MIPS reporting for clinicians who currently utilize qualified registries or QCDRs that have not previously offered the ability to report Promoting Interoperability or improvement activity data. We believe it is also possible that some MIPS eligible clinicians may elect to begin utilizing qualified registries or QCDRs as a result this policy and its potential for simplifying their MIPS reporting combined with the benefits of improving the quality of care provided to their patients. We do not have information with which to estimate the number of clinicians who may pursue this option, therefore we cannot quantify the associated costs, cost savings, and benefits consistent with the CY 2018 Quality Payment Program final rule (82 FR 53946).

(2) Potential Costs of Compliance With Improvement Activities Performance Category

In section III.K.3.c.(3)(d)(iii) of this final rule, we are: (1) Modifying the definition of rural area; (2) updating § 414.1380(b)(3)(ii)(A) and (C) removing the reference to the four listed accreditation organizations to be recognized as patient-centered medical homes and removing the reference to the specific accrediting organization for comparable specialty practices; (3) increasing the group reporting threshold to 50 percent; (4) establishing factors to consider for removal of improvement activities from the Inventory; (5) removing 15, modifying seven, and adding two new improvement activities for the 2020 performance period and future years; and (6) concluding and removing the CMS Study on Factors Associated with Reporting Quality Measures.

The finalized proposals to modify the definition of a rural area and to remove references to the four listed accreditation organizations to be recognized as patient-centered medical homes and to the specific accrediting organization for comparable specialty practices will have no financial impact due to the nature of the regulatory changes being finalized.

Given groups' familiarity with the improvement activities in the Improvement Activities Inventory, we believe that a group would find applicable and meaningful activities to complete that are not specific to practice size, specialty, or practice setting and would apply to at least 50 percent of individual MIPS eligible clinicians in the group. Therefore, an increase in the minimum threshold for a group to receive credit for the improvement activities performance category should not present additional complexity or burden. We also anticipate that the vast majority of clinicians performing improvement activities, to comply with existing MIPS policies, would continue to perform the same activities under the policies established in this final rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rule-making (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the 2020 MIPS performance period. Of the activities that are being removed, or modified, many were duplicative which means many clinicians or groups would be able to continue the activity, but it would be reported under a different activity in the Improvement Activities Inventory.

Our provision to establish removal factors for consideration when removing improvement activities from the Improvement Activities Inventory would provide guidance for clinicians or groups on the considerations for the removal of improvement activities and would not present additional burden. The changes to the Improvement Activities Inventory that include the modification, removal, and addition of improvement activities provide clarity, avoid duplication, and provide more options for clinicians to select improvement activities that are appropriate for their clinical practice and would not present additional burden. Furthermore, in this final rule, we end and remove the Study on Factors Associated with Reporting Quality Measures beginning with the 2020 MIPS performance period. In the CY 2019 PFS final rule, we finalized a sample size of 200 clinicians, each of which completed a 15-minute survey both prior to and after submitting MIPS data (83 FR 60058). As a result of ending the study, we estimate a reduction in burden of 100 hours and $20,286 (200 clinicians × 0.5 hours × $202.86).

(3) Potential Costs of Compliance With the Cost Performance Category

We state in section VI.B.7.j of the CY 2020 PFS final rule that there were no submissions required for the cost performance categories, therefore, we did not include any compliance cost associated with that performance category; however, we received the following comments on administrative costs for the cost performance category proposals.

Comment: One commenter noted that in a large multi-specialty organization the number of cost measures could increase administrative burden on clinicians and organizations, to track measures and work to improve performance.

Response: We acknowledge there are administrative burdens and related financial costs associated with each administrative claims measure clinicians, groups, and organizations may choose to monitor. However, because these costs can vary significantly due to organizational size, number of administrative claims measures being reported, volume of clinicians reporting each measure, and the specific methods employed to improve performance, we are unable to provide an estimate of the financial impact each clinician, group, or organization may experience.

As a result of these comments, we are acknowledging that while there is no data collection burden, there may be associated costs for clinicians and group practices to monitor new cost measures; however, we are unable to quantify that impact.

f. Potential Costs of Compliance for Third Party Intermediaries

Based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088), the current policy is that all third party intermediaries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. As previously discussed in section III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this final rule, we are finalizing changes to § 414.1400(a)(2) to state that beginning with the 2023 MIPS payment year (2021 performance period), QCDRs and qualified registries must be able to submit data for all the MIPS performance categories identified in the regulation. In section III.K.3.g.(1) of this final rule, we further state that we anticipate using the QCDR and qualified registry self-nomination vetting process to assess which of these entities will be subject to the requirement to support reporting the Promoting Interoperability performance category and which third parties could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) or (5) or § 414.1380(c)(2)(i)(C)(1) through (7) or (9). Based on our review of qualified registries and QCDRs approved to submit data for the 2019 MIPS performance period, 70 percent of qualified registries and 72 percent of QCDRs are already able to submit data for the quality, improvement activities, and Promoting Interoperability performance categories. We believe this provision could result in the remaining qualified registries and QCDRs incurring additional costs to upgrade information technology systems in order to make this ability available to clinicians, with less cost incurred by entities who would be subject to an exception for the Promoting Interoperability performance category. However, given that each of these entities and their information technology systems are unique, and there is no method of determining which entities may have already begun the process of developing this ability, we are unable to determine the impact of transitioning from allowing this ability as an option to requiring it. Also, given that the majority of these entities have already begun offering the ability to submit data on behalf of the improvement activities and Promoting Interoperability performance categories, we assume they have done so because they believe the benefits outweigh the costs and is therefore, in their best financial interests to do so.

In section III.K.3.g.(3)(a)(iii) of this final rule, beginning with the 2021 performance period, we require qualified registries and QCDRs to provide the following as part of the performance feedback given at least 4 times a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure and/or QCDR measure) within the QCDR. We understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. As finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77367 through 77386 and 82 FR 53812), qualified registries and QCDRs are required to provide feedback on all of the MIPS performance categories that the qualified registry or QCDR reports at least 4 times a year. Given that we did not propose a significant change but are instead modifying and strengthening the existing policy, we do not anticipate a significant increase in cost or effort for Third Party Intermediaries to comply with this provision.

In section III.K.3.g.(3)(c)(i)(B)(cc), we require that in order for a QCDR measure to be considered for use in the program beginning with the 2021 performance period and future years, all QCDR measures submitted for self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System, as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. Beginning with the 2021 performance period and future years, we also require QCDRs to collect data on the potential QCDR measure, appropriate to the measure type, as defined in the CMS Blueprint for the CMS Measures Management System, prior to self-nomination. The testing process for quality measures is dependent on the measure type (for example, a measure that is specified as an eCQM measure has additional steps it must undergo when compared to other measure types). The National Quality Forum (NQF) has developed guides for measure testing criteria and standards which further illustrate these differences based on measure type.[134] Additionally, the costs associated with testing vary based on the complexity of the measure and the developing organization. The Journal of the American Medical Association states that the costs associated with quality measures are generally unknown or unreported.[135] While we understand the policy will result in additional costs for QCDRs to develop measures, given the uncertainty regarding the number and types of measures that will be proposed in future performance periods coupled with the lack of available cost data on measure development and testing, we are unable to determine the financial impact of this provision on QCDRs beyond the likelihood of it being more than trivial. Likewise, we understand that some QCDRs already perform measure testing prior to submission for approval while others do not. This variability makes it difficult to estimate the incremental impact of this regulation.

In section III.K.3.g.(3)(c)(i)(A)(bb)(AA) of this rule, we amend § 414.1400 to state that CMS may consider the extent

[134] *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx.*

[135] Schuster, Onorato, and Meltzer. ''Measuring the Cost of Quality Measurement: A Missing Link in Quality Strategy'', Journal of the American Medical Association. 2017; 318(13):1219–1220. *https://jamanetwork.com/journals/jama/fullarticle/2653111?resultClick=1.*

to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. Because the choice to license a QCDR measure is an elective business decision made by individual QCDRs and we have little insight into both the specific terms and frequency of agreements made between entities, we are unable to account for the financial impact of licensing QCDR measures for each QCDR. In aggregate across all QCDRs, the financial impact would be zero as fees paid by one QCDR will be collected by another QCDR.

In section III.K.3.g.(3)(c)(i)(B)(ee) of this rule, we discuss, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. We are unable to account for the financial impact of measure harmonization, as the process and outcomes will likely vary substantially depending on a number of factors, including: Extent of duplication with other measures, number of QCDRs involved in harmonizing toward a single measure, and number of measures being harmonized among the same QCDRs. We intend to identify only those QCDR measures which are duplicative to such an extent as to assume harmonization will not be overly burdensome, however, because the harmonization process will occur between QCDRs without our involvement, we are unable to predict or quantify the associated effort.

We understand that some QCDRs may believe the provisions to require measure harmonization and encourage QCDRs to license their measures to other QCDRs as a consideration for measure approval may result in a reduced ability for QCDRs to differentiate themselves in the marketplace. We note that in addition to the suite of measures offered by a QCDR and their relevance to individual clinicians and groups, ease of incorporating a QCDR's measures into existing practice workflows, as well as integration into broader quality improvement programs are two examples of distinguishing characteristics for clinicians to consider when selecting a QCDR. In addition, clinicians may also consider cost (if any); recommendations, support, or endorsements from specialty societies; the number of other users submitting data to the QCDR; the specific educational services and quality improvement initiatives offered; and the specific performance feedback information provided as part of the required reports provided at least 4 times a year. We believe that the impact these provisions may have on the perceived differentiated value of certain QCDRs is counterbalanced by the need to promote more focused quality measure development towards outcomes that are meaningful to patients, families and their providers.

In this final rule, we discussed our policy to formalize a number of factors we would take into consideration for approving and rejecting QCDR measures for the MIPS program beginning with the 2020 performance period and future years. With regard to approving QCDR measures, we are implementing the following: (1) 2-year QCDR measure approval process, and (2) participation plan for existing QCDR measures that have failed to reach benchmarking thresholds.

As discussed in section III.K.3.g.(3)(c)(ii)(B), we are implementing, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described in section III.K.3.g.(3)(c). The 2-year approvals would be subject to the following conditions whereby the multi-year approval will no longer apply if the QCDR measure is identified as: Topped out; duplicative of a new, more robust measure; reflects an outdated clinical guideline; requires measure harmonization, or if the QCDR self-nominating the measure is no longer in good standing. We believe this will result in reduced burden for QCDRs as they will no longer be required to submit each measure for approval annually. However, because we are unable to predict which previously approved QCDR measures will be removed or retained in future years, we are likewise unable to predict the impact on future burden associated with QCDRs submitting measures for approval. Beginning with the 2021 performance period, we require that in instances where an existing QCDR measure has been in MIPS for 2 years and has failed to reach benchmarking thresholds due to low adoption, where the QCDR believes the low-reported QCDR measure is still important and relevant to a specialist's practice, that the QCDR may submit to CMS a QCDR measure participation plan, to be submitted as part of their self-nomination. Because we are unable to predict the frequency with which existing QCDR measures will meet the criteria for allowing QCDRs to submit a measure participation plan or the likelihood of QCDRs electing to submit a plan, we are unable to estimate the impact associated with this provision.

As discussed in section III.K.3.g.(3)(c)(i)(B)(bb) of this final rule, beginning with the 2021 performance period and future years, QCDRs must link their QCDR measures as feasible to the following, at the time of self-nomination: (a) Cost measures (as found in section III.K.3.c.(3) of this final rule), (b) improvement activities (as found in Appendix 2: Improvement Activities Tables), or (c) CMS developed MIPS Value Pathways (as described in section III.K.3.a. of this final rule). We do not assume any additional impact beyond the 1 hour per QCDR measure as discussed in section VI.B.7 of the Collection of Information section of this final rule.

We are also finalizing in section III.K.3.g.(2) of this final rule and at § 414.1400(a)(4) to establish that a condition of approval is for the third party intermediary to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan. Historically, less than 10 third party intermediaries have elected to discontinue services during a performance period and we have no basis to assume this is likely to change in future years. We do not assume any additional impact beyond the 10 hours per transition plan discussed in section VI.B.7 of this final rule.

We are finalizing in section III.K.3.g.3(c)(i)(A)(bb)(BB) of this final rule to amend § 414.1400 to add paragraph (b)(3)(iv)(I) to state that we would give greater consideration to measures for which QCDRs: (a) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and (b) utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development. We are also finalizing in section III.K.3.g.3(c)(i)(A)(bb)(CC) of this final rule and § 414.1400 to add paragraph (b)(3)(iv)(J), to state that, beginning with the 2020 performance period, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not meet this requirement, may not continue to be approved. Lastly, we are finalizing in section III.K.3.g.3(c)(i)(B)(aa) of this final rule, beginning with the 2020 performance period, to change both of the below listed considerations into requirements and add paragraph (b)(3)(v) to include the following for QCDR measure requirements for approval: Measures that are beyond the measure concept phase of development; and measures that address significant variation in performance. We do not assume any additional impacts beyond those previously discussed in this section or in the Collection of Information section.

We received public comments on the compliance costs for third party intermediaries. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed their opinion that the scope of proposals in the proposed rule increases cost and burden to the point where some third-party vendors may end their participation in MIPS. One commenter stated that several provisions would additionally require it to alter business plans, missions, and customer service priorities while another commenter cited their belief that CMS is attempting to shift costs and burden of administering the MIPS program onto specialty societies that create measures and operate QCDRs.

Response: We disagree. We believe that our policies are intended to standardize and raise the bar on the services and the quality of the third-party intermediaries we have in the MIPS program. Similar to years past, the standards and requirements of QCDRs are higher when compared to that of qualified registries, as we expect QCDRs to have extensive experience in quality reporting, quality measure development, and clinical expertise to not just facilitate reporting, but to also help address measurement gaps found within the program. We believe that QCDRs and qualified registries should further clinician goals of quality improvement by providing meaningful information and services. We believe that the increased cost and burden are significantly outweighed by the positive impact of the policies for MIPS eligible clinicians. As a result of the comments, we have not updated our estimates.

g. Assumptions & Limitations

We note several limitations to our estimates of MIPS eligible clinicians' eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the 2022 MIPS payment year. We based our analyses on the data prepared to support the 2018 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*),[136] APM Participant List for the first snapshot date for the 2019 QP performance period, CY 2018 Quality Payment Program Year 2 data and CAHPS for ACOs. The scoring model results presented in this rule assume that CY 2018 Quality Payment Program Year 2 data submissions and performance are representative of CY 2020 Quality Payment Program data submissions and performance. The estimated performance for CY 2020 MIPS performance period using Quality Payment Program Year 2 data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2018 MIPS performance period/2019 MIPS payment year was significantly lower (15 out of 100 points) than the performance threshold for the 2020 MIPS performance period/2022 MIPS payment year (45 out of 100). We anticipate clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that 33 percent of the opt-in eligible clinicians that participated in the CY 2018 Quality Payment Program Year 2 would elect to opt-in to the MIPS program. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the finalized policies.

A limitation of our cost data is that it does not overlap with the 2018 calendar year so we may not be capturing performance for all clinicians.

There are additional limitations to our estimates: (1) Because we used historic data, we assumed participation in the three performance categories in MIPS Year 2 would be similar to MIPS Year 4 performance; and (2) to the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 123. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify in detail.

G. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, would result in different payment rates, and therefore, result in different estimates than those shown in Table 119 (CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty).

1. Alternatives Considered Related to Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs

We considered several possibilities for pricing the oral medications, namely methadone and buprenorphine (oral), included in the OTP payment bundles. As described in section II.G. of this final rule, we finalized the use of ASP-based payment to set the payment rates for the oral OTP drug product categories when we receive manufacturer-submitted ASP data for these drugs and to limit the payment amounts for oral drugs to 100 percent of the ASP instead of 106 percent of the ASP. When ASP data are not available for the oral OTP drugs, we finalized use of the TRICARE rate to set the drug portion of the payment for

[136] The time period for this eligibility file (September 1, 2016 to August 31, 2017) maximizes the overlap with the performance data in our model.

methadone and the NADAC data to set the drug portion of the payment for oral buprenorphine. We note that, for the CY 2020 payments, we were able to calculate an ASP for methadone because of manufacturer reporting. However, we did not receive ASP data from any of the buprenorphine oral manufacturers. Therefore, this drug category was priced using NADAC survey data.

In developing the policies for this final rule, we also considered several other options for pricing of oral drugs as described in the proposed rule, including the methodology under section 1847A of the Act; Medicare Part D Prescription Drug Plan Finder data; WAC; and NADAC data. In determining which alternative data source to finalize for pricing the oral OTP drugs, in the event we did not receive manufacturer-submitted ASP pricing data, we considered commenters' varied responses to the options presented in the proposed rule. We also considered the possibility of using the TRICARE rate for methadone as the primary pricing methodology and increasing the payment limits to 106 percent of the ASP, instead of 100 percent of the ASP, as suggested by commenters.

We did not receive comments that would significantly alter our assumptions regarding estimated impacts of these alternatives. For methadone, using the methodology under section 1847A of the Act, Medicare Part D Prescription Drug Plan Finder data, WAC, TRICARE rates, and NADAC data methodologies would have resulted in a slightly decreased impact when compared to the reported ASP. For buprenorphine (oral), the Medicare Part D Prescription Drug Plan Finder data is very similar to NADAC pricing. Therefore, we believe there would be minimal changes in the estimated impacts from using this alternative data source. Since WAC-based pricing is slightly higher than NADAC pricing, we note that using WAC-based pricing would increase the estimated impacts marginally. For both oral product categories, increasing the payment limit to 106 percent of the ASP, instead of 100 percent of the ASP, would have resulted in a correspondingly higher impact.

While considering whether to finalize the rates that were proposed for the non-drug component, we explored a number of alternative scenarios based on commenters' responses to our proposals. For example, we considered whether to finalize the proposed rate that was based on a crosswalk to TRICARE's bundled weekly rate for methadone, whether to base the Medicare rate on the rates set by state Medicaid programs, or whether to calculate the rate using a building block methodology which sums the payment rates for similar services paid under Medicare currently. Were we to have finalized the proposed rates that were based on a crosswalk to TRICARE's weekly bundled rate, that would have resulted in a lower impact compared to the estimated impact of the rates we are finalizing, which were calculated using a building block methodology, as the TRICARE rate for non-drug services is lower than the rate we have finalized using the building block approach. Were we to have finalized rates equal to those set by some state Medicaid programs, the estimated impact would vary depending on which state Medicaid programs were used.

We note that there is significant variability across the state Medicaid programs in terms of the payment rates and what services are included in the bundle or billed separately, and that some states have payment rates that are higher than our finalized rate. Additionally, we considered whether to finalize partial episodes for each of the bundled payments. Were we to have finalized partial episodes that would have likely resulted in a lower overall impact compared to the rates we are finalizing, as the rates that were proposed for the partial episodes were calculated by taking one half of the value of the non-drug component for the full episodes. As noted in section II.G of this rule, we are not finalizing our proposal to create partial episodes for CY 2020.

We also considered several alternatives for the update factor used in updating the payment rates for the non-drug component of the bundled payment for OUD treatment services, including the Bureau of Labor Statistics Consumer Price Index for All Items for Urban Consumers (CPI–U) (Bureau of Labor Statistics #CUUR0000SA0 (*https://www.bls.gov/cpi/data.htm*)) and the IPPS hospital market basket reduced by the multifactor productivity adjustment. Based on a CMS forecast of projected rates, we believe that the projected MEI and CPI–U rates are anticipated to be similar, and thus using the CPI–U as an update factor would have minimal effect on estimated impacts. Since the projected IPPS hospital market basket rate is generally higher than the projected MEI rate, using the IPPS hospital market basket rate would result in higher estimated impacts. We received one comment which stated that an OTP's cost structure is more similar to a hospital outpatient department than a physician's office, so the IPPS annual update factor should be used instead of the MEI rate. In considering the appropriate update factor to finalize, we considered the medical services being provided by the OTP facilities and we believe that conceptually physician office services more closely align to OTP services, and compositionally the MEI more closely aligns with the services associated with the OTP payment system.

2. Alternatives Considered Related to Payment for E/M Services

In developing our policies for office/outpatient E/M visits effective January 1, 2021, we considered a number of alternatives. For reasons discussed in section II.P. of this final rule, we did not include either the extended office/outpatient E/M HCPCS code GPR01 or the single blended payment rates for combined visit levels 2 through 4 that were finalized in the CY 2019 final rule for CY 2021 in our considerations. Our alternatives also did not include the revaluation of global surgical services, as recommended by the AMA RUC, which incorporated the revised office/outpatient E/M code values. We note that in all of the alternatives we considered, the valuation for all codes in the office/outpatient E/M code set would increase. Therefore, all specialties for whom the office/outpatient codes represent a significant portion of their billing would also see payment increases while those specialties who do not report those codes would see overall payment decreases. Any variation in the magnitude of the increases or decreases are a result of a specialties overall billing patterns.

We did, however, consider proposing to eliminate both add-on codes, HCPCS code GCG0X and HCPCS code GPC1X, that were finalized in the CY 2019 final rule for CY 2021. Our stated rationale in the CY 2019 final rule for developing HCPCS code GPC1X (83 FR 59625 through 59653) was to more accurately account for the type and intensity of E/M work performed in primary care-focused visits beyond the typical resources reflected in the single payment rate for the levels 2 through 4 visits. The reason for finalizing HCPCS code GCG0X, as stated in the CY 2019 FR (83 FR 59625 through 59653) GCG0X was to reflect additional resource costs for inherently complex services that are non-procedural. We considered whether these two add-on codes would still be necessary in the context of the revised descriptors and valuations for office/outpatient E/M services. We considered an alternative, therefore, in which we adopted the RUC's recommended values

but excluded the two HCPCS add-on G-codes. In reviewing the results of this policy option, we observed that our concerns about capturing the work associated with visits that are part of ongoing, comprehensive primary care and/or care management for patients having a single, serious, or complex chronic condition were still present. The specialty level impacts associated with this alternative are displayed in Table 124. The specialties that benefited most from this alternative, such as Endocrinology and Rheumatology, are those that primarily bill levels 3–5 established patient office/outpatient E/M visits, as those visit levels had the greatest increases in valuation among the overall office/outpatient E/M code set.

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TABLE 124: Estimated Specialty Specific Impacts of Accepting the RUC Recommended Values but Deleting Both HCPCS G codes GCG0X and GPC1X if Implemented in CY 2020

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	3%	3%	0%	6%
Anesthesiology	$1,993	-3%	-1%	0%	-4%
Audiologist	$70	-3%	-1%	0%	-4%
Cardiac Surgery	$279	-4%	-1%	-1%	-5%
Cardiology	$6,595	1%	1%	0%	1%
Chiropractor	$750	-4%	-2%	-1%	-7%
Clinical Psychologist	$787	-4%	0%	0%	-4%
Clinical Social Worker	$781	-4%	1%	0%	-4%
Colon And Rectal Surgery	$162	-1%	0%	0%	-1%
Critical Care	$346	-3%	-1%	0%	-3%
Dermatology	$3,541	1%	2%	-1%	2%
Diagnostic Testing Facility	$697	0%	-3%	0%	-3%
Emergency Medicine	$3,021	-3%	-1%	1%	-4%
Endocrinology	$488	7%	3%	1%	10%
Family Practice	$6,019	5%	2%	0%	7%
Gastroenterology	$1,713	0%	0%	-1%	-1%
General Practice	$405	3%	1%	0%	5%
General Surgery	$2,031	-1%	0%	0%	-2%
Geriatrics	$187	1%	1%	0%	2%
Hand Surgery	$226	0%	1%	0%	1%
Hematology/Oncology	$1,673	5%	2%	1%	8%
Independent Laboratory	$592	-2%	0%	0%	-2%
Infectious Disease	$640	-2%	-1%	0%	-3%
Internal Medicine	$10,507	1%	1%	0%	2%
Interventional Pain Mgmt	$885	2%	2%	0%	4%
Interventional Radiology	$432	-2%	-2%	0%	-4%
Multispecialty Clinic/Other Phys	$148	0%	0%	0%	0%
Nephrology	$2,164	-1%	0%	0%	-1%
Neurology	$1,503	1%	4%	0%	6%
Neurosurgery	$802	-2%	0%	-1%	-3%
Nuclear Medicine	$50	-2%	0%	0%	-2%
Nurse Anes / Anes Asst	$1,291	-5%	-1%	0%	-6%
Nurse Practitioner	$4,503	2%	1%	0%	4%
Obstetrics/Gynecology	$620	2%	2%	0%	4%
Ophthalmology	$5,398	-3%	-4%	0%	-7%
Optometry	$1,325	0%	-2%	0%	-2%
Oral/Maxillofacial Surgery	$71	0%	0%	-1%	-1%
Orthopedic Surgery	$3,734	0%	1%	0%	1%
Other	$34	-1%	-1%	0%	-2%
Otolaryngology	$1,225	2%	1%	0%	3%
Pathology	$1,203	-3%	-2%	0%	-5%
Pediatrics	$62	2%	1%	0%	3%
Physical Medicine	$1,110	0%	0%	0%	0%
Physical/Occupational Therapy	$4,248	-3%	-2%	0%	-5%
Physician Assistant	$2,637	2%	1%	0%	4%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Plastic Surgery	$369	-1%	0%	-1%	-2%
Podiatry	$1,998	2%	2%	0%	4%
Portable X-Ray Supplier	$94	-1%	-1%	0%	-3%
Psychiatry	$1,120	2%	1%	0%	3%
Pulmonary Disease	$1,658	0%	0%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-1%	-1%	0%	-2%
Radiology	$4,971	-3%	-2%	0%	-5%
Rheumatology	$534	6%	3%	1%	9%
Thoracic Surgery	$352	-3%	-1%	0%	-5%
Urology	$1,739	2%	2%	0%	5%
Vascular Surgery	$1,203	-1%	-2%	0%	-3%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

We also considered, as an alternative, proposing CMS refinements to the RUC recommendations for two of the CPT codes. Consistent with our generally established policies for reviewing work RVUs recommended by the RUC, we observed that the increase in work RVU for CPT codes 99212 and 99214 (levels 2 and 4 for established patients) seemed disproportionate to the increase in total time for these services, particularly in comparison with the work to time relationships among the other seven E/M code revaluations. For CPT code 99212, we observed that the total time for furnishing this service increased by 2 minutes (13 percent increase), but that the recommended work RVU increased by nearly 50 percent from 0.48 to 0.70. We reviewed other CPT codes with similar times as the survey code and identified a potential crosswalk to CPT code 76536 (*Ultrasound, soft tissues of head and neck e.g., thyroid, parathyroid, parotid), real time with image documentation*), with a work RVU of 0.56. We therefore considered decreasing the work RVU for CPT code 99212 to 0.56. For CPT code 99214, the total time increased from 40 to 49 minutes, which is a 23 percent change, while the work RVU increased from 1.50 to 1.92 (28 percent increase). We considered a crosswalk to CPT code 73206 (*Computed tomographic angiography, upper extremity, with contrast material(s), including noncontrast images, if performed, and image postprocessing*), with a work RVU of 1.81 and total time of 50 minutes. The refinements we considered for the RUC recommendations are shown in Table 125.

TABLE 125: Current, RUC recommended and CMS Refined Office/Outpatient E/M Work RVUs

CPT/HCPCS	Current Work RVU (Current)	RUC-Recommended Work RVU	Alternative: CMS-Refined Work RVU
99201	0.48	NA	NA
99202	0.93	0.93	0.93
99203	1.42	1.6	1.6
99204	2.43	2.6	2.6
99205	3.17	3.5	3.5
99211	0.18	0.18	0.18
99212	0.48	0.7	0.56
99213	0.97	1.3	1.3
99214	1.5	1.92	1.81
99215	2.11	2.8	2.8
99XXX	NA	0.61	0.5
GPC1X	0.25	NA	0.33
GCG0X	0.25	NA	0.33

Table 126 illustrates the specialty level impacts of refining the RUC recommendations. Under this alternative those specialties who frequently bill CPT code 99212 or CPT code 99214, such as dermatology and family practice, respectively, experience more modest increases relative to other alternatives.

TABLE 126: Estimated Specialty Specific Impacts of CMS Refined Values if Implemented in CY 2020

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	3%	3%	0%	6%
Anesthesiology	$1,993	-3%	-1%	0%	-4%
Audiologist	$70	-2%	-1%	0%	-4%
Cardiac Surgery	$279	-3%	-1%	0%	-5%
Cardiology	$6,595	1%	1%	0%	1%
Chiropractor	$750	-3%	-2%	-1%	-6%
Clinical Psychologist	$787	-4%	0%	0%	-3%
Clinical Social Worker	$781	-4%	1%	0%	-3%
Colon And Rectal Surgery	$162	-1%	0%	0%	-1%
Critical Care	$346	-2%	-1%	0%	-3%
Dermatology	$3,541	1%	2%	-1%	2%
Diagnostic Testing Facility	$697	0%	-3%	0%	-3%
Emergency Medicine	$3,021	-3%	-1%	1%	-3%
Endocrinology	$488	5%	2%	1%	8%
Family Practice	$6,019	4%	2%	1%	6%
Gastroenterology	$1,713	0%	0%	-1%	-1%
General Practice	$405	3%	1%	0%	4%
General Surgery	$2,031	-1%	0%	0%	-2%
Geriatrics	$187	1%	1%	0%	2%
Hand Surgery	$226	0%	1%	0%	1%
Hematology/Oncology	$1,673	5%	2%	1%	8%
Independent Laboratory	$592	-2%	0%	0%	-2%
Infectious Disease	$640	-2%	0%	0%	-2%
Internal Medicine	$10,507	1%	1%	0%	2%
Interventional Pain Mgmt	$885	2%	2%	1%	4%
Interventional Radiology	$432	-1%	-2%	0%	-4%
Multispecialty Clinic/Other Phys	$148	0%	0%	0%	0%
Nephrology	$2,164	-1%	0%	0%	-1%
Neurology	$1,503	1%	4%	0%	5%
Neurosurgery	$802	-1%	0%	-1%	-3%
Nuclear Medicine	$50	-2%	0%	0%	-2%
Nurse Anes / Anes Asst	$1,291	-4%	-1%	0%	-5%
Nurse Practitioner	$4,503	2%	1%	0%	4%
Obstetrics/Gynecology	$620	2%	2%	0%	4%
Ophthalmology	$5,398	-3%	-4%	0%	-7%
Optometry	$1,325	0%	-2%	0%	-2%
Oral/Maxillofacial Surgery	$71	0%	0%	-1%	-1%
Orthopedic Surgery	$3,734	0%	1%	0%	1%
Other	$34	-1%	-1%	0%	-2%
Otolaryngology	$1,225	2%	2%	0%	3%
Pathology	$1,203	-3%	-2%	0%	-5%
Pediatrics	$62	2%	1%	0%	3%
Physical Medicine	$1,110	0%	0%	0%	1%
Physical/Occupational Therapy	$4,248	-3%	-2%	0%	-5%
Physician Assistant	$2,637	2%	1%	0%	4%
Plastic Surgery	$369	-1%	0%	-1%	-2%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Podiatry	$1,998	2%	2%	0%	4%
Portable X-Ray Supplier	$94	-1%	-1%	0%	-2%
Psychiatry	$1,120	1%	1%	0%	3%
Pulmonary Disease	$1,658	0%	0%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-1%	-1%	0%	-2%
Radiology	$4,971	-3%	-2%	-1%	-5%
Rheumatology	$534	5%	2%	1%	8%
Thoracic Surgery	$352	-3%	-1%	0%	-4%
Urology	$1,739	2%	2%	0%	5%
Vascular Surgery	$1,203	-1%	-2%	0%	-3%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

We also considered an alternative that reflected CMS refinements to the three CPT codes as described above and also included the consolidated, redefined and revalued HCPCS add-on G code, GPC1X.

Table 127 illustrates the specialty level impacts associated with making refinements to the RUC recommended values for the office/outpatient E/M code set and also making separate payment for HCPCS add-on code GPC1X. These impacts are similar to what we proposed, with slight less positive impacts for those specialties who bill CPT codes 99212 or 99214.

TABLE 127: Estimated Specialty Specific Impacts of CMS Refined Values with HCPCS add-on G code GPC1X if Implemented in CY 2020

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	3%	3%	0%	7%
Anesthesiology	$1,993	-5%	-1%	0%	-6%
Audiologist	$70	-4%	-2%	0%	-6%
Cardiac Surgery	$279	-5%	-2%	-1%	-7%
Cardiology	$6,595	1%	1%	0%	3%
Chiropractor	$750	-5%	-3%	-1%	-9%
Clinical Psychologist	$787	-6%	0%	0%	-6%
Clinical Social Worker	$781	-6%	0%	0%	-6%
Colon And Rectal Surgery	$162	-3%	0%	0%	-3%
Critical Care	$346	-4%	-1%	0%	-5%
Dermatology	$3,541	0%	1%	-1%	-1%
Diagnostic Testing Facility	$697	0%	-3%	0%	-4%
Emergency Medicine	$3,021	-5%	-2%	1%	-6%
Endocrinology	$488	10%	4%	1%	15%
Family Practice	$6,019	7%	3%	1%	11%
Gastroenterology	$1,713	-2%	-1%	-1%	-4%
General Practice	$405	5%	2%	0%	7%
General Surgery	$2,031	-3%	-1%	0%	-4%
Geriatrics	$187	1%	2%	0%	3%
Hand Surgery	$226	-1%	0%	0%	-1%
Hematology/Oncology	$1,673	7%	4%	1%	12%
Independent Laboratory	$592	-2%	-1%	0%	-4%
Infectious Disease	$640	-2%	0%	0%	-3%
Internal Medicine	$10,507	2%	2%	0%	4%
Interventional Pain Mgmt	$885	4%	3%	1%	8%
Interventional Radiology	$432	-2%	-3%	0%	-5%
Multispecialty Clinic/Other Phys	$148	-2%	0%	0%	-2%
Nephrology	$2,164	-2%	0%	0%	-2%
Neurology	$1,503	2%	5%	0%	8%
Neurosurgery	$802	-3%	-1%	-2%	-6%
Nuclear Medicine	$50	-3%	0%	0%	-4%
Nurse Anes / Anes Asst	$1,291	-6%	-2%	0%	-8%
Nurse Practitioner	$4,503	4%	3%	0%	7%
Obstetrics/Gynecology	$620	4%	3%	0%	7%
Ophthalmology	$5,398	-4%	-5%	0%	-9%
Optometry	$1,325	-2%	-3%	0%	-5%
Oral/Maxillofacial Surgery	$71	-1%	-1%	-1%	-3%
Orthopedic Surgery	$3,734	-1%	0%	0%	-2%
Other	$34	-3%	-2%	0%	-5%
Otolaryngology	$1,225	3%	2%	0%	5%
Pathology	$1,203	-4%	-3%	-1%	-8%
Pediatrics	$62	3%	2%	0%	5%
Physical Medicine	$1,110	-2%	0%	0%	-2%
Physical/Occupational Therapy	$4,248	-4%	-4%	0%	-8%
Physician Assistant	$2,637	4%	2%	0%	7%
Plastic Surgery	$369	-2%	-1%	-1%	-4%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Podiatry	$1,998	0%	1%	0%	1%
Portable X-Ray Supplier	$94	-1%	-3%	0%	-4%
Psychiatry	$1,120	4%	3%	0%	7%
Pulmonary Disease	$1,658	0%	1%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-2%	-2%	0%	-4%
Radiology	$4,971	-4%	-3%	0%	-8%
Rheumatology	$534	8%	4%	1%	13%
Thoracic Surgery	$352	-4%	-2%	-1%	-7%
Urology	$1,739	4%	4%	0%	8%
Vascular Surgery	$1,203	-2%	-3%	0%	-4%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

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Comment: As discussed previously, some commenters questioned the necessity of additional coding to describe medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. Some commenters encouraged CMS to work with CPT and the RUC, rather than utilize Medicare specific G-codes, to address concerns regarding payment for these services. Other commenters rejected the necessity of additional payment all together.

Response: Please see the full discussion in section II.P. of this final rule. We continue to believe that the revalued office/outpatient E/M visits do not accurately account for the resources associated with furnishing primary care and certain types of specialty visits.

Comment: Overall, commenters did not support CMS' refinements to the valuation of CPT codes 99212 and 99214 as reflected in alternatives considered, stating that the values recommended to CMS by the RUC were more accurate as they were part of a rigorous survey and represented a consensus by the medical community.

Response: As discussed in section II.P. of this final rule, we agree with commenters and are finalizing as proposed.

3. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold and the additional performance threshold, as the critical factors affecting the distribution of payment adjustments. We ran two separate models with performance thresholds of 35 and 50 respectively (as an alternative to the proposed performance threshold of 45) to estimate the impact of a more moderate and a more aggressive increase in the performance threshold. A lower performance threshold would be a more gradual transition and could potentially allow more clinicians to meet or exceed the performance threshold. The lower performance threshold would lower the amount of budget neutral dollars to redistribute and increase the number of clinicians with a positive payment adjustment, but the scaling factor would be lower. In contrast, a more aggressive increase would likely lead to higher positive payment adjustments for clinicians that exceed the performance threshold because the budget neutral pool would be redistributed among fewer clinicians. We ran each of these models using the proposed additional performance threshold of 85. In the model with a performance threshold of 35, we estimate that $360 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 6.0 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 5.2 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with a performance threshold of 50, we estimate that $470 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 6.4 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 9.6 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. We proposed a performance threshold of 45 because we believe increasing the performance threshold to 45 points was not unreasonable or too steep, but rather a moderate step that encourages clinicians to gain experience with all MIPS performance categories. We refer readers to section III.K.3.e.(2) of this final rule for additional rationale on the selection of the performance threshold.

To evaluate the impact of modifying the additional performance threshold, we ran two models with additional performance thresholds of 75 and 80 as an alternative to the 85 points. We ran each of these models using a performance threshold of 45. The benefit of the model with the additional performance threshold of 75 would maintain the additional performance threshold that was in year 3. In the model with the additional performance threshold of 75, we estimate that $433 million would be redistributed through budget neutrality, and there would be a maximum payment adjustment of 3.8 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 7.5 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with an additional performance threshold of 80, we estimate that $433 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 4.5 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance among those that submit data. Also, that 7.5 percent of MIPS eligible clinicians will receive a negative payment adjustment among those that submit data. We proposed the additional performance threshold at 85 points because we believe raising the additional performance threshold would

incentivize continued improved performance while accounting for policy changes in the fourth year of the program. We refer readers to section III.K.3.e.(3) of this final rule for additional rationale on the selection of additional performance threshold.

In addition, we ran a model with a weight of 20 percent for the cost performance category and of 40 percent for the quality performance category as an alternate to our finalized weight of 15 percent for the cost performance category. The 20 percent weight for the cost performance category has a mean score of 76.34 and a median score of 82.88 where our primary model has a mean score of 76.67 and a median score of 83.57.

H. Impact on Beneficiaries

1. Medicare PFS

There are a number of changes in this final rule that will have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, will have a positive impact and improve the quality and value of care provided to Medicare providers and beneficiaries.

2. Quality Payment Program

There are several changes in this rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new measures include patient-reported outcomes, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcomes are factors frequently of interest to patients when making decisions about treatment. Similarly, our provisions in section III.K.3.g.(3) of this rule will improve the caliber and value of QCDR measures.

I. Burden Reduction Estimates: Payment for E/M Services

In the CY 2019 PFS final rule, we finalized proposals that we made in response to comments received from RFIs released to the public under our Patients Over Paperwork Initiative. Specifically, we finalized provisions that focused on simplifying the medical documentation payment framework for office/outpatient E/M services and allowing greater flexibility on the components practitioners could choose to document when billing Medicare for office/outpatient E/M visits. In that rule we discussed the specific changes to documentation requirements and estimated significant reductions in the amount of time that practitioners would spend documenting office/outpatient E/M visits, furthering our goal of allowing practitioners more time spent with patients. As discussed earlier in section II.P. of this final rule, we proposed to adopt the revised office/outpatient E/M code set. The proposals reflected our ongoing dialog with the practitioner community and took into account the significant revisions the AMA/CPT Editorial Panel has made to the guidelines for the office/outpatient E/M code set. We note that as part of its efforts to revise the guidelines, the AMA has also estimated a reduction in the amount of time practitioners would spend documenting office/outpatient E/M visits. The AMA asserts that its revisions to the office/outpatient E/M code set will accomplish similar, albeit greater burden reduction in comparison with CMS' approach, as finalized in the CY 2019 PFS final rule, and is more intuitive and in line with the current practice of medicine. We reviewed the AMA's estimates and acknowledge that overall the AMA's approach does result in burden reduction that are consistent with our broader goals discussed above. In comparison to our estimates of burden reduction, as discussed in the CY 2019 final rule, the AMA's estimates show less documentation burden to practitioners, the difference resulting from CMS' finalized policies that allow use of add-on codes to reflect additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits that the current E/M coding and visit levels do not fully recognize (FR 83 59638). The AMA estimates reflect assumptions that the time spent documenting appropriate application of the add-on codes may result in additional burden to practitioners. We disagree with this assumption. In addition to proposing to redefine and revalue HCPCS G code add-on GPC1X to be more understandable and easy to report for purposes of medical documentation and billing, and proposing to delete HCPCS G-code add-on GCG0X, we discussed that we believe that while an initial setup period is expected for practices to establish workflows that incorporate appropriate use of the add-on code, practices should be able to automate the appropriate use of the add-on code in a short period of time. Even so, our proposal to adopt the AMA's revised office/outpatient E/M code set was consistent with our goal of burden reduction and aligns with the policy principles that underlay what we finalized in the CY 2019 PFS final rule. The AMA's estimates of burden reduction as related to office/outpatient E/M documentation and other materials pertinent to the AMA/CPT and AMA/RUC's recent efforts to revise the office/outpatient E/M code set are available at *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management.* The burden estimates as discussed above remain the same because we made no refinements to our proposals to adopt the AMA's revised office/outpatient E/M code set.

J. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review this rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the May 2018 BLS for medical and health service managers (Code 11–9111), we

estimate that the cost of reviewing this rule is $109.36 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $874.88 (8.0 hours × $109.36). Therefore, we estimated that the total cost of reviewing this regulation is $37,997,788 ($874.88 × 43,432 reviewers).

K. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 128 and 129 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2019 to CY 2020 based on the FY 2020 President's Budget baseline.

TABLE 128—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2020 Annualized Monetized Transfers	Estimated increase in expenditures of $0.3 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 129—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2020 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion.
From Whom to Whom?	Beneficiaries to Federal Government.

L. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 403.902 is amended—
■ a. By adding in alphabetical order the definitions of ''Certified nurse midwife'', ''Certified registered nurse anesthetist'', and ''Clinical nurse specialist'';
■ b. By revising the definition of ''Covered recipient'';
■ c. By adding in alphabetical order the definitions of ''Device identifier'', ''Long term medical supply or device loan'', ''Non-teaching hospital covered recipient'', ''Nurse practitioner'', ''Physician assistant'', ''Short term medical supply or device loan'', and ''Unique device identifier''.

The additions and revisions read as follows:

§ 403.902 Definitions.

* * * * *

Certified nurse midwife means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

Certified registered nurse anesthetist means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the

Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

* * * * *

Clinical nurse specialist means, an individual who—

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(2) Holds a master's degree in a defined clinical area of nursing from an accredited educational institution.

* * * * *

Covered recipient means—

(1) Any physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse-midwife who is not a bona fide employee of the applicable manufacturer that is reporting the payment; or

Device identifier is the mandatory, fixed portion of a unique device identifier (UDI) that identifies the specific version or model of a device and the labeler of that device (as described at 21 CFR 801.3 in paragraph (1) of the definition of ''Unique device identifier'').

* * * * *

Long term medical supply or device loan means the loan of supplies or a device for 91 days or longer.

Non-teaching hospital covered recipient means a person who is one or more of the following: Physician; physician assistant; nurse practitioner; clinical nurse specialist; certified registered nurse anesthetist; or certified nurse-midwife.

* * * * *

Nurse practitioner means a nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

* * * * *

Physician assistant means a physician assistant who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

* * * * *

Short term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.

* * * * *

Unique device identifier means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 801.40 and 830.3.

■ 3. Section 403.904 is amended by—

■ a. Revising paragraphs (c)(1), (c)(3) introductory text, (c)(3)(ii) and (iii), (c)(8), (e)(2) introductory text and;

■ b. Adding paragraph (e)(2)(xi);

■ c. Revising paragraphs (e)(2)(xiv) and (xv);

■ d. Adding paragraph (e)(2)(xviii); and

■ e. Revising paragraphs (f)(1) introductory text, (f)(1)(i)(A) introductory text, (f)(1)(i)(A)(*1*),(*3*) and (5), (f)(1)(iv), (f)(1)(v), (h)(5), (h)(7), and (h)(13).

The revisions and addition read as follows:

§ 403.904 Reports of payments or other transfers of value to covered recipients.

* * * * *

(c)* * *

(1) *Name of the covered recipient.* For non-teaching hospital covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (NPPES) (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

* * * * *

(3*) Identifiers for non-teaching hospital covered recipients.* In the case of a covered recipient the following identifiers:

* * * * *

(ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a non-teaching hospital covered recipient, the field may be left blank, indicating that the applicable manufacturer could not find one.

(iii) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license), and the State(s) in which the license is held.

* * * * *

(8) *Related covered drug, device, biological or medical supply.* Report the marketed or brand name of the related covered drugs, devices, biologicals, or medical supplies, and therapeutic area or product category unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply.

(i) For drugs and biologicals—

(A) If the marketed name has not yet been selected, applicable manufacturers must indicate the name registered on *clinicaltrials.gov*.

(B) Any regularly used identifiers must be reported, including, but not limited to, national drug codes.

(ii) For devices, if the device has a unique device identifier (UDI), then the device identifier (DI) portions of it must be reported, as applicable.

(iii) Applicable manufacturers may report the marketed name and therapeutic area or product category for payments or other transfers of value related to a non-covered drug, device, biological, or medical supply.

(iv) Applicable manufacturers must indicate if the related drug, device, biological, or medical supply is covered or non-covered.

(v) Applicable manufacturers must indicate if the payment or other transfer of value is not related to any covered or non-covered drug, device, biological or medical supply.

* * * * *

(e) * * *

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xviii) of this section, using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

* * * * *

(xi) Debt forgiveness.

* * * * *

(xiv) Compensation for serving as faculty or as a speaker for a medical education program.

(xv) Long term medical supply or device loan.

* * * * *

(xviii) Acquisitions.

(f) * * *

(1) Research-related payments or other transfers of value to covered recipients, including research-related

payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)):

(i) * * *

(A) If paid to a non-teaching hospital covered recipient, all of the following must be provided:

(*1*) The non-teaching hospital covered recipient's name as listed in the NPPES (if applicable).

* * * * *

(*3*) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license) and State(s) in which the license is held.

* * * * *

(*5*) Primary business address of the non-teaching hospital covered recipient(s).

* * * * *

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section); for drugs and biologicals, the relevant National Drug Code(s), if any; and for devices and medical supplies, the relevant device identifier, if any, and the therapeutic area or product category if a marketed name is not available.

(v) Information about each non-teaching hospital covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

* * * * *

(h) * * *

(5) Short term medical supply or device loan.

* * * * *

(7) A transfer of anything of value to a non-teaching hospital covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

* * * * *

(13) In the case of a non-teaching hospital covered recipient, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

* * * * *

■ 4. Section 403.908 is amended by revising paragraphs (g)(2)(ii) introductory text to read as follows:

§ 403.908 Procedures for electronic submission of reports.

* * * * *

(g) * * *

(2) * * *

(ii) Covered recipients—

* * * * *

PART 409—HOSPITAL INSURANCE BENEFITS

■ 5. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 409.27 [Amended]

■ 6. Section 409.27 is amended in paragraph (c) by removing the reference ''§ 410.40(d)(1)'' and adding in its place the reference ''§ 410.40(e)(1)''.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 7. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 8. Section 410.20 is amended by adding paragraph (e) to read as follows:

§ 410.20 Physicians' services.

* * * * *

(e) *Medical record documentation.* The physician may review and verify (sign/date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team including, as applicable, notes documenting the physician's presence and participation in the services.

■ 9. Section 410.40 is amended—

■ a. By redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively;

■ b. By adding new paragraph (a);

■ c. In newly redesignated paragraph (b)(1) by removing the reference ''paragraphs (d) and (e)'' and adding in its place the reference ''paragraphs (e) and (f)''; and

■ d. By revising newly redesignated paragraphs (e)(2)(i), (e)(3)(i), and (e)(3)(iii) through (v).

The additions and revision reads as follows:

§ 410.40 Coverage of ambulance services.

(a) *Definitions.* As used in this section, the following definitions apply:

Non-physician certification statement means a statement signed and dated by an individual which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met and who meets all of the criteria in paragraphs (i) through (iii) of this definition. The statement need not be a stand-alone document and no specific format or title is required.

(i) Has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished;

(ii) Who must be employed:

(A) By the beneficiary's attending physician; or

(B) By the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported;

(iii) Is among the following individuals, with respect to whom all Medicare regulations and all applicable State licensure laws apply:

(A) Physician assistant (PA).

(B) Nurse practitioner (NP).

(C) Clinical nurse specialist (CNS).

(D) Registered nurse (RN).

(E) Licensed practical nurse (LPN).

(F) Social worker.

(G) Case manager.

(H) Discharge planner.

Physician certification statement means a statement signed and dated by the beneficiary's attending physician which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met. The statement need not be a stand-alone document and no specific format or title is required.

* * * * *

(e) * * *

(2) * * *

(i) Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a physician certification statement dated no earlier than 60 days before the date the service is furnished.

* * * * *

(3) * * *

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a physician certification statement within 48 hours after the transport.

* * * * *

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a non-physician certification statement must be obtained.

(iv) If the ambulance provider or supplier is unable to obtain the required physician or non-physician certification statement within 21 calendar days following the date of the service, the ambulance provider or supplier must document its attempts to obtain the

requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (e)(3)(iii) of this section.

(v) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the physician or non-physician certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

* * * * *

■ 10. Section 410.41 is amended by revising the section heading and paragraph (c)(1) to read as follows:

§ 410.41 Requirements for ambulance providers and suppliers.

* * * * *

(c) * * *

(1) Bill for ambulance services using CMS-designated procedure codes to describe origin and destination and indicate on claims form that the physician certification statement or non-physician certification statement is on file, if required.

* * * * *

■ 11. Section 410.49 is amended by revising paragraph (b)(1)(vii) and adding paragraph (b)(1)(viii) to read as follows:

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

* * * * *

(b) * * *

(1) * * *

(vii) Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014 for cardiac rehabilitation and on or after February 9, 2018 for intensive cardiac rehabilitation; or

(viii) Other cardiac conditions as specified through a national coverage determination (NCD). The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

* * * * *

■ 12. Section 410.59 is amended by—

■ a. Adding paragraphs (a)(4) and (e)(1)(v); and

■ b. Revising paragraphs (e)(2) introductory text, (e)(2)(i) and (v), and (e)(3).

The additions and revisions read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(4) Effective for dates of service on and after January 1, 2020, for occupational therapy services described in paragraph (a)(3)(i) or (ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by an occupational therapy assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, ''furnished in whole or in part'' means when the occupational therapy assistant either:

(A) Furnishes all the minutes of a service exclusive of the occupational therapist; or

(B) Furnishes a portion of a service separately from the part furnished by the occupational therapist such that the minutes for that portion of a service furnished by the occupational therapy assistant exceed 10 percent of the total minutes for that service.

* * * * *

(e) * * *

(1) * * *

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is no longer applied as a limitation on incurred expenses for outpatient occupational therapy services, but, is instead applied as a threshold above which claims for occupational therapy services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record and claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient occupational therapy includes:

(i) Outpatient occupational therapy services furnished under this section;

* * * * *

(v) Outpatient occupational therapy services furnished by a CAH directly or under arrangements, included in the amount of annual incurred expenses as if such services were furnished under section 1834(k)(1)(B) of the Act.

* * * * *

(3) A process for medical review of claims for outpatient occupational therapy services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at or in excess of $3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the $3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the $3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process applies when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, $3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the medical review threshold in effect for the previous year (starting with $3,000 in 2027) by the increase in the Medicare Economic Index for the current year.

■ 13. Section 410.60 is amended by—

■ a. Adding paragraphs (a)(4) and (e)(1)(v); and

■ b. Revising paragraphs (e)(2) introductory text, (e)(2)(i), (ii) and (vi), and (e)(3).

The additions and revisions read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(4) Effective for dates of service on and after January 1, 2020, for physical therapy services described in paragraphs (a)(3)(i) or (ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by a physical therapist assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, ''furnished in whole or in part'' means when the physical therapist assistant either:

(A) Furnishes all the minutes of a service exclusive of the physical therapist; or

(B) Furnishes a portion of a service separately from the part furnished by the physical therapist such that the minutes for that portion of a service furnished by the physical therapist assistant exceed 10 percent of the total minutes for that service.

* * * * *

(e) * * *

(1) * * *

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is not applied as a limitation on incurred expenses for outpatient physical therapy and outpatient speech-language pathology services, but is instead applied as a threshold above which claims for physical therapy and speech-language pathology services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record; and claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient physical therapy includes:

(i) Outpatient physical therapy services furnished under this section;

(ii) Outpatient speech-language pathology services furnished under § 410.62;

* * * * *

(vi) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements, included in the amount of annual incurred expenses as if such services were furnished and paid under section 1834(k)(1)(B) of the Act.

(3) A process for medical review of claims for physical therapy and speech-language pathology services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at or in excess of $3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the $3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the $3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, $3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the medical review threshold in effect for the previous year (starting with $3,000 for 2017) by the increase in the Medicare Economic Index for the current year.

■ 14. Section 410.67 is added to read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

(a) *Basis and scope.* (1) *Basis.* This section implements sections 1861(jjj), 1861(s)(2)(HH), 1833(a)(1)(CC) and 1834(w) of the Act which provide for coverage of opioid use disorder treatment services furnished by an opioid treatment program and the payment of a bundled payment under Part B to an opioid treatment program for opioid use disorder treatment services that are furnished to a beneficiary during an episode of care beginning on or after January 1, 2020.

(2) *Scope.* This section sets forth the criteria for an opioid treatment program, the scope of opioid use disorder treatment services, and the methodology for determining the bundled payments to opioid treatment programs for furnishing opioid use disorder treatment services.

(b) *Definitions.* For purposes of this section, the following definitions apply:

Episode of care means a one-week (contiguous 7-day) period.

Opioid treatment program means an entity that is an opioid treatment program (as defined in § 8.2 of this title, or any successor regulation) that meets the requirements described in paragraph (c) of this section.

Opioid use disorder treatment service means one of the following items or services for the treatment of opioid use disorder that is furnished by an opioid treatment program that meets the requirements described in paragraph (c) of this section.

(1) Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug, and Cosmetic Act for use in treatment of opioid use disorder.

(2) Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.

(3) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements.

(4) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements.

(5) Toxicology testing.

(6) Intake activities, including initial medical examination services required under § 8.12(f)(2) of this title and initial assessment services required under § 8.12(f)(4) of this title.

(7) Periodic assessment services required under § 8.12(f)(4) of this title.

(c) *Requirements for opioid treatment programs.* To participate in the Medicare program and receive payment, an opioid treatment program must meet all of the following:

(1) Be enrolled in the Medicare program.

(2) Have in effect a certification by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the opioid treatment program.

(3) Be accredited by an accrediting body approved by the SAMHSA.

(4) Have in effect a provider agreement under part 489 of this title.

(d) *Bundled payments for opioid use disorder treatment services furnished by opioid treatment programs.*

(1) CMS will establish categories of bundled payments for opioid treatment programs for an episode of care as follows:

(i) Categories for each type of opioid agonist and antagonist treatment medication;

(ii) A category for medication not otherwise specified, which will be used for new FDA-approved opioid agonist or antagonist treatment medications for which CMS has not established a category; and

(iii) A category for episodes of care in which no medication is provided.

(2) The bundled payment for episodes of care in which a medication is provided consists of payment for a drug component, reflecting payment for the applicable FDA-approved opioid agonist or antagonist medication in the patient's treatment plan, and a non-drug component, reflecting payment for all other opioid use disorder treatment services reflected in the patient's treatment plan (including dispensing/administration of the medication, if applicable). The payments for the drug component and non-drug component are added together to create the bundled payment amount. The bundled payment

for episodes of care in which no medication is provided consists of a single payment amount for all opioid use disorder treatment services reflected in the patient's treatment plan (excluding medication and dispensing/administration of medication).

(i) *Drug component.* The payment for the drug component for an episode of care will be determined as follows, using the most recent data available at time of ratesetting for the applicable calendar year:

(A) For implantable and injectable medications, the payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount shall be 100 percent of the ASP, if ASP is used.

(B) For oral medications, if ASP data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in part 414, subpart 800 of this chapter and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate and for buprenorphine will be calculated using the National Average Drug Acquisition Cost.

(C) *Exception.* For the drug component of bundled payments in the medication not otherwise specified category under paragraph (d)(1)(iii) of this section, the payment amount is be based on the applicable methodology under paragraphs (d)(2)(i)(A) and (B) of this section (applying the most recent available data for such new medication), or invoice pricing until the necessary data become available.

(ii) *Non-drug component.* The payment for CY 2020 for the non-drug component of the bundled payment for an episode of care is the sum of:

(A) The CY 2019 Medicare physician fee schedule non-facility rates for the following items and services:

(*1*) Psychotherapy, 30 minutes with patient

(*2*) Group psychotherapy

(*3*) Alcohol and/or substance (other than tobacco) abuse structured assessment and brief intervention at the non-physician practitioner rate.

(*4*) For administration of an injectable medication, if applicable, drug administration (Therapeutic, prophylactic).

(*5*) For the insertion, removal, or insertion and removal of the implantable medication, if applicable, the applicable rate.

(B) For dispensing oral medication, if applicable, an approximation of the average dispensing fees under state Medicaid programs.

(C) One fourth of the sum of the CY 2019 Clinical Laboratory Fee Schedule rate for two drug tests, presumptive, capable of being read by direct optical observation only and for a drug test, definitive, 1–7 drug classes.

(iii) *No medication provided episodes of care.* The bundled payment amount for CY 2020 for an episode of care in which no medication is provided is based on the non-drug component rate for an episode of care in which a drug is dispensed or administered, not including any amounts reflecting the cost of dispensing or administration of a drug.

(3) At least one OUD treatment service described in paragraphs (b)(1) through (5) of this section must be furnished to bill for the bundled payment for an episode of care.

(4) Adjustments will be made to the bundled payment for the following:

(i) If the opioid treatment program furnishes:

(A) Counseling or therapy services in excess of the amount specified in the beneficiary's treatment plan and for which medical necessity is documented in the medical record, an adjustment will be made for each additional 30 minutes of counseling or individual therapy furnished during the episode of care.

(B) Intake activities described in paragraph (b)(6) of this section, an adjustment will be made when intake activities are furnished.

(C) Periodic assessments described in paragraph (b)(7) of this section, an adjustment will be made when this service is furnished.

(D) Additional take home supply of oral drugs of up to 21 days, in increments of 7 days, an adjustment will be made when oral medications are dispensed.

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, and the adjustments for counseling or therapy, intake activities and periodic assessments will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26 of this chapter.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, and the adjustments for counseling or therapy, intake activities and periodic assessments will be updated annually using the Medicare Economic Index described in § 405.504(d) of this chapter.

(5) Payment for medications delivered, administered or dispensed to a beneficiary as part of the bundled payment is considered a duplicative payment if a claim for delivery, administration or dispensing of the same medications for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. CMS will recoup the duplicative payment made to the opioid treatment program.

(e) *Beneficiary cost-sharing.* A beneficiary copayment amount of zero will apply.

■ 15. Section 410.69 is amended in paragraph (b) by adding paragraph (5) to the definition of ''Certified registered nurse anesthetist'' to read as follows:

§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

* * * * *

(b) * * *

Certified registered nurse anesthetist * * *

(5) For certified registered nurse anesthetist services, the certified registered nurse anesthetist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the certified registered nurse anesthetist's presence and participation in the service.

* * * * *

■ 16. Section 410.74 is amended by revising paragraph (a)(2)(iv) and by adding paragraph (e) to read as follows:

§ 410.74 Physician assistants' services.

(a) * * *

(2) * * *

(iv) Performs the services in accordance with state law and state scope of practice rules for physician assistants in the state in which the physician assistant's professional services are furnished. Any state laws and scope of practice rules that describe the required practice relationship between physicians and physician assistants, including explicit supervisory or collaborative practice requirements, describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Act. For states with no explicit state law and scope of practice rules regarding physician supervision of physician assistant's services, physician supervision is a process in which a physician assistant has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting at the

practice level the physician assistant's scope of practice and the working relationships the physician assistant has with the supervising physician/s when furnishing professional services.

* * * * *

(e) *Medical record documentation.* For physician assistants' services, the physician assistant may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the physician assistant's presence and participation in the service.

■ 17. Section 410.75 is amended by adding paragraph (f) to read as follows:

§ 410.75 Nurse practitioners' services.

* * * * *

(f) *Medical record documentation.* For nurse practitioners' services, the nurse practitioner may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the nurse practitioner's presence and participation in the service.

■ 18. Section 410.76 is amended by adding paragraph (f) to read as follows:

§ 410.76 Clinical nurse specialists' services.

* * * * *

(f) *Medical record documentation.* For clinical nurse specialists' services, the clinical nurse specialist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the clinical nurse specialist's presence and participation in the service.

■ 19. Section 410.77 is amended by adding paragraph (e) to read as follows:

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

* * * * *

(e) *Medical record documentation.* For certified nurse-midwives' services, the certified nurse-midwife may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the certified nurse-midwife's presence and participation in the service.

■ 20. Section 410.105 is amended by adding paragraph (d) to read as follows:

§ 410.105 Requirements for coverage of CORF services.

* * * * *

(d) *Claims.* Effective for dates of service on and after January 1, 2020 physical therapy or occupational therapy services covered as part of a rehabilitation plan of treatment described in paragraph (c) of this section, as applicable—

(1) Claims for such services furnished in whole or in part by a physical therapist assistant or an occupational therapy assistant must be identified with the inclusion of the respective prescribed modifier; and

(2) Effective for dates of service on and after January 1, 2022, such claims are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service as defined at section 1834(k) of the Act.

(3) For purposes of this paragraph, ''furnished in whole or in part'' means when the physical therapist assistant or occupational therapy assistant either—

(i) Furnishes all the minutes of a service exclusive of the respective physical therapist or occupational therapist; or

(ii) Furnishes a portion of a service separately from the part furnished by the physical or occupational therapist such that the minutes for that portion of a service exceed 10 percent of the total time for that service.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 21. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 22. Section 411.370 is amended—

■ a. In paragraph (b) introductory text, by removing the phrase ''CMS determines'' and adding in its place the phrase ''CMS will determine''; and

■ b. By revising paragraphs (b)(1), (c) introductory text, (d), and (e).

The revisions read as follows:

§ 411.370 Advisory opinions relating to physician referrals.

* * * * *

(b) * * *

(1) The request must relate to an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. CMS does not consider, for purposes of an advisory opinion, requests that involve the activities of third parties.

* * * * *

(c) *Matters not subject to advisory opinions.* CMS will not address through an advisory opinion—

* * * * *

(d) *Facts subject to advisory opinions.* The requestor must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in § 411.372.

(e) *Acceptance of requests.* (1) CMS does not accept an advisory opinion request or issue an advisory opinion if—

(i) The request is not related to a named individual or entity;

(ii) The request does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information;

(iii) CMS is aware, after consultation with OIG and DOJ, that the same course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency;

(iv) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry; or

(v) CMS determines that the arrangement or course of conduct at issue is or would be in violation of applicable State or Federal law or regulation.

(2) CMS may elect not to accept an advisory opinion request if it determines, after consultation with OIG and DOJ:

(i) The course of action described is substantially similar to a course of conduct that is under investigation or the subject of a proceeding involving the Department or other law enforcement agencies; and

(ii) Issuing an advisory opinion could interfere with the investigation or proceeding.

* * * * *

■ 23. Section 411.372 is amended by—

■ a. Revising paragraphs (b)(4)(i) and (ii), (5), (6), and (8)(ii);

■ b. Removing paragraph (b)(9); and

■ c. Adding paragraph (d).

The revisions and addition read as follows:

§ 411.372 Procedure for submitting a request.

* * * * *

(b) * * *

(4) * * *

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including:

(A) The purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved); and

(B) Any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal service or employment contracts, leases, deeds, pension or insurance plans, or financial statements (or, if these relevant documents do not yet exist, a complete description, to the best of the requestor's knowledge, of what these documents are likely to contain);

* * * * *

(5) The identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and § 411.354), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) At the option of the requestor, a discussion of the specific issues or questions to be addressed by CMS including, if possible, a discussion of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

* * * * *

(8) * * *

(ii) The chief executive officer, or other authorized officer, of the requestor, if the requestor is a corporation;

* * * * *

(d) *Requests for expedited review.* Parties may seek expedited review of arrangements under § 411.380(c)(1)(i) for a determination as to whether the arrangement or course of conduct is indistinguishable in all material aspects from an arrangement or course of conduct that was the subject of a prior advisory opinion. Parties seeking such expedited review must identify the relevant advisory opinion and provide an explanation of why the subject arrangement is indistinguishable from the arrangement that was the subject of the prior relevant advisory opinion. Requestors should clearly and prominently indicate in their submission to CMS that they are seeking expedited review.

■ 24. Section 411.375 is amended by—

■ a. Revising paragraphs (a);

■ b. Removing paragraph (b); and

■ c. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c).

The revision reads as follows:

§ 411.375 Fees for the cost of advisory opinions.

(a) *Hourly rate.* CMS will charge an hourly rate of $220. Parties may request an estimate from CMS after submitting a complete request. Before issuing the advisory opinion, CMS will calculate the final fee for responding to the request.

* * * * *

■ 25. Section 411.379 is amended by revising paragraphs (a), (b), (d) and (e) to read as follows:

§ 411.379 When CMS accepts a request.

(a) Upon receiving a request for an advisory opinion, CMS promptly makes an initial determination of whether the request contains a level of detail sufficient for CMS to process the request.

(b) If CMS determines that the request submitted lacks details necessary for CMS to process the request, CMS will provide notification to the requestor within 15 working days of receiving the request.

* * * * *

(d) CMS formally accepts a request when CMS determines that the request (inclusive of any supplemental submissions) describes the arrangement at issue with sufficient detail and that the grounds for rejection of a request listed at § 411.370(e) do not apply. Upon accepting the request, CMS notifies the requestor by regular U.S. mail of the date that CMS formally accepts the request.

(e) The applicable time period that CMS has to issue an advisory opinion set forth in § 411.380(c) does not begin until CMS formally accepts the request for an advisory opinion.

■ 26. Section 411.380 is amended by revising paragraph (c) to read as follows:

§ 411.380 When CMS issues a formal advisory opinion.

* * * * *

(c)(1) Except as set forth in paragraph (c)(2) of this section, CMS issues an advisory opinion in accordance with the provisions of this part within 60 working days after the date on which it formally accepts the advisory opinion request.

(i) In the case of a request for a determination that an arrangement or course of conduct is indistinguishable in all material aspects from another arrangement or course of conduct that was the subject of a prior opinion, CMS issues an advisory opinion within 30 working days after the date on which it formally accepts the advisory opinion request.

(ii) In the case of a request that CMS determines, in its discretion, involves complex legal issues or highly complicated fact patterns, CMS issues an advisory opinion within a reasonable time period after the date on which it formally accepts the advisory opinion request.

(iii) If the last day of the 60-working day or 30-working day time period falls on a Saturday, Sunday, or Federal holiday, CMS may issue the advisory opinion at the close of business on the first business day following the weekend or holiday.

(2) The applicable time period for issuing an advisory opinion is suspended from the time CMS;

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in § 411.375(c)(2) until CMS receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until CMS receives the additional information;

(iii) Notifies the requestor of the full amount due until CMS receives payment of this amount; and

(iv) Notifies the requestor of the need for expert advice until CMS receives the expert advice.

* * * * *

■ 27. Section 411.382 is revised to read as follows:

§ 411.382 CMS' right to rescind advisory opinions.

(a)(1) Any advice CMS gives in an advisory opinion does not prejudice its right to reconsider the questions involved in the opinion, and CMS may rescind or revoke the opinion if it determines that there is good cause to rescind or revoke the opinion.

(2) Good cause shall exist where—

(i) There is a material change in the law that affects the conclusions reached in an opinion; or

(ii) A party that has received a negative advisory opinion seeks reconsideration based on new facts or law.

(b) CMS provides advance notice to the requestor and to the public of its decision to rescind or revoke the opinion so that the requestor and other parties may discontinue any course of action they have taken in accordance with, or in good faith reliance on, the advisory opinion.

(c) CMS does not proceed against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon CMS' advice under this part, provided—

(1) The requestor presented to CMS a full, complete and accurate description of all the relevant facts; and

(2) The parties promptly discontinue the action upon receiving notice that CMS had rescinded or revoked its approval, or discontinue the action within a reasonable ''wind down'' period, as determined by CMS.

§ 411.384 [Amended]

■ 28. Section 411.384 is amended in paragraph (b) by removing the phrase ''for public inspection during its normal hours of operation and''.

■ 29. Section 411.387 is revised to read as follows:

§ 411.387 Effect of an advisory opinion.

(a) An advisory opinion is binding on the Secretary, and a favorable advisory opinion shall preclude imposition of sanctions under section 1877(g) of the Act with respect to:

(1) The individuals or entities requesting the opinion; and

(2) Individuals or entities that are parties to the specific arrangement with respect to which such advisory opinion has been issued.

(b) The Secretary will not pursue sanctions under section 1877(g) of the Act against any party to an arrangement that CMS determines is indistinguishable in all its material aspects from an arrangement with respect to which CMS issued a favorable advisory opinion.

(c) Individuals and entities may rely on an advisory opinion as non-binding guidance that illustrates the application of the physician self-referral law and regulations to the specific facts and circumstances described in the advisory opinion.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 30. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 31. Section 414.601 is amended by adding the following sentence to the end of the section:

§ 414.601 Purpose.

* * * Section 1834(l)(17) of the Act requires the development of a data collection system to collect cost, revenue, utilization, and other information determined appropriate from providers of services and suppliers of ground ambulance services.

■ 32. Section 414.605 is amended by—

■ a. Adding the definition of ''Ground ambulance organization'' in alphabetical order; and

■ b. In the definition of ''Paramedic ALS intercept (PI)'' by removing the reference ''§ 410.40(c)'' and adding in its place the reference ''§ 410.40(d)''.

The addition reads as follows:

§ 414.605 Definitions.

* * * * *

Ground ambulance organization means a Medicare provider or supplier of ground ambulance services.

* * * * *

■ 33. Section 414.610 is amended by adding paragraph (c)(9) to read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(9) *Payment reduction for failure to report data.* In the case of a ground ambulance organization (as defined at § 414.605) that is selected by CMS under § 414.626(c) for a year that does not sufficiently submit data under § 414.626(b) and is not granted a hardship exemption under § 414.626(d), the payments made under this section are reduced by 10 percent for the applicable period. For purposes of this paragraph, the applicable period is the calendar year that begins following the date that CMS provided written notification to the ground ambulance organization under § 414.626(e)(1) that the ground ambulance did not sufficiently submit the required data.

* * * * *

■ 34. Section 414.626 is added to subpart H to read as follows:

§ 414.626 Data reporting by ground ambulance organizations.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Data collection period means, with respect to a year, the 12-month period that reflects the ground ambulance organization's annual accounting period.

Data reporting period means, with respect to a year, the 5-month period that begins the day after the last day of the ground ambulance organization's data collection period.

For a year means one of the calendar years from 2020 through 2024.

Medicare Ground Ambulance Data Collection Instrument means the single survey-based data collection instrument that can be accessed by sampled ambulance organizations under this section via a secure web-based system for reporting data under this section.

(b) *Data collection and submission requirement.* Except as provided in paragraph (d) of this section, a ground ambulance organization selected by CMS under paragraph (c) of this section must do the following:

(1) Within 30 days of the date that CMS notifies a ground ambulance organization under paragraph (c)(3) of this section that it has selected the ground ambulance organization to report data under this section, the ground ambulance must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to the ground ambulance organization's Medicare Administrative Contractor.

(2) Collect during its selected data collection period the data necessary to complete the Medicare Ground Ambulance Data Collection Instrument.

(3) Submit to CMS a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to the ground ambulance organization's selected data collection period.

(c) *Representative sample.* (1) *Random sample.* For purposes of the data collection described in paragraph (b) of this section, and for a year, CMS will select a random sample of 25 percent of eligible ground ambulance organizations that is stratified based on:

(i) Provider versus supplier status and ownership (for-profit, non-profit, and government);

(ii) Service area population density (transports originating in primarily urban, rural, and super rural zip codes); and

(iii) Medicare-billed transport volume categories.

(2) *Selection eligibility.* A ground ambulance organization is eligible to be selected for data reporting under this section for a year if it is enrolled in Medicare and has submitted to CMS at least one Medicare ambulance transport claim during the year prior to the selection under paragraph (b)(1) of this section.

(3) *Notification of selection for a year.* CMS will notify an eligible ground ambulance organization that it has been selected to report data under this section for a year at least 30 days prior to the beginning of the calendar year in which the ground ambulance organization must begin to collect data by posting a list of selected organizations on the CMS web page and providing written notification to each selected ground ambulance organization via email or U.S. mail.

(4) *Limitation.* CMS will not select the same ground ambulance organization under this paragraph (c) in 2 consecutive years, to the extent practicable.

(d) *Hardship exemption.* A ground ambulance organization selected under paragraph (c) of this section may request and CMS may grant an exception to the reporting requirements under paragraph (b) of this section in the event of a significant hardship, such as a natural disaster, bankruptcy, or similar situation that the Secretary determines interfered with the ability of the ground ambulance organization to submit such information in a timely manner for the data collection period selected by the ground ambulance organization.

(1) To request a hardship exemption, the ground ambulance organization must submit a request form (accessed on the Ambulances Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*) to CMS within 90 calendar days of the date that CMS notified the ground ambulance organization that it would receive a 10 percent payment reduction as a result of not submitting sufficient information under the data collection system. The request form must include all of the following:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Ground ambulance organization address.

(iv) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable).

(v) Reason for requesting a hardship exemption.

(vi) Evidence of the impact of the hardship (such as photographs, newspaper or other media articles, financial data, bankruptcy filing, etc.).

(vii) Date when the ground ambulance organization would be able to begin collecting data under paragraph (b) of this section.

(viii) Date and signature of the chief executive officer or other designated personnel of the ground ambulance organization.

(2) CMS will provide a written response to the hardship exemption request within 30 days of its receipt of the hardship exemption form.

(e) *Notification of non-compliance and informal review.* (1) *Notification of non-compliance.* A ground ambulance organization selected under paragraph (c) of this section for a year that does not sufficiently report data under paragraph (b) of this section, will receive written notification from CMS that it will receive a payment reduction under § 414.610(c)(9).

(2) *Informal review.* A ground ambulance organization that receives a written notification under paragraph (e)(1) of a payment reduction under § 414.610(c)(9) may submit a request for an informal review within 90 days of the date it received the notification by submitting all of the following information:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address with the street location of the ground ambulance organization.

(iv) Ground ambulance organization's selected data collection period and data reporting period.

(v) A statement of the reasons why the ground ambulance organization does not agree with CMS' determination and any supporting documentation.

(f) *Public availability of data.* Beginning in 2022, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

(g) *Limitations on review.* There is no administrative or judicial review under section 1869 or section 1878 of the Act, or otherwise of the data required for submission under paragraph (b) of this section or the selection of ground ambulance organizations under paragraph (c) of this section.

■ 35. Section 414.1305 is amended by—

■ a. Adding the definition of ''Aligned Other Payer Medical Home Model'' in alphabetical order;

■ b. Revising the definition of ''Hospital-based MIPS eligible clinician'';

■ c. Adding the definition of ''MIPS Value Pathway'' in alphabetical order; and

■ d. Revising the definition of ''Rural area''.

The additions and revision read as follows:

§ 414.1305 Definitions.

* * * * *

Aligned Other Payer Medical Home Model means an aligned other payer payment arrangement (not including a Medicaid payment arrangement) operated by a payer formally partnering in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation, such as a memorandum of understanding (MOU) with CMS, and is determined by CMS to have the following characteristics:

(1) The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity of care.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

* * * * *

Hospital-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus-outpatient hospital, or emergency room setting based on claims for a period prior to the performance period as specified by CMS; and

(2) For the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period; and

(3) Beginning with the 2022 MIPS payment year, an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period.

* * * * *

MIPS Value Pathway means a subset of measures and activities established through rulemaking.

* * * * *

Rural area means a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

* * * * *

■ 36. Section 414.1310 is amended by—

■ a. Revising paragraph (e)(2)(ii); and

■ b. Removing paragraphs (e)(3) through (5).

The revision reads as follows:

§ 414.1310 Applicability.

* * * * *

(e) * * *

(2) * * *

(ii) Individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT.

* * * * *

■ 37. Section 414.1315 is amended by revising paragraph (d)(2) to read as follows:

§ 414.1315 Virtual groups.

* * * * *

(d) * * *

(2) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.

* * * * *

■ 38. Section 414.1320 is amended by adding paragraph (f) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(f) For purposes of the 2023 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 39. Section 414.1330 is amended by revising paragraphs (b)(3) to read as follows:

§ 414.1330 Quality performance category.

* * * * *

(b) * * *

(3) 45 percent of a MIPS eligible clinician's final score for MIPS payment years 2021 and 2022.

■ 40. Section 414.1335 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) * * *

(3) * * *

(i) For the 12-month performance period, a group that participates in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

* * * * *

■ 41. Section 414.1340 is amended by revising paragraphs (a)(1) and (2) and adding paragraphs (a)(3), (b)(3), and (d) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) * * *

(1) At least 50 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2019.

(2) At least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2020 and 2021.

(3) At least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2022 MIPS payment year.

(b) * * *

(3) At least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2022 MIPS payment year.

* * * * *

(d) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

■ 42. Section 414.1350 is amended by revising paragraphs (b), (c)(2) and (d)(3) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(b) *Attribution.* (1) Cost measures are attributed at the TIN/NPI level for the 2017 thorough 2019 performance periods.

(2) For the total per capita cost measure specified for the 2017 through 2019 performance periods, beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter.

(3) For the Medicare Spending per Beneficiary clinician (MSPB clinician) measure specified for the 2017 through 2019 performance periods, an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB clinician measure during the applicable performance period.

(4) For the acute condition episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills at least 30 percent of

inpatient evaluation and management (E/M) visits during the trigger event for the episode.

(5) For the procedural episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills a Medicare Part B claim with a trigger code during the trigger event for the episode.

(6) For the acute inpatient medical condition episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who bills inpatient E/M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E/M claim lines in that hospitalization.

(7) For the procedural episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

(8) Beginning with the 2020 performance period, each cost measure is attributed according to the measure specifications for the applicable performance period.

* * * * *

(c) * * *

(2) For the Medicare spending per beneficiary clinician measure, the case minimum is 35.

* * * * *

(d) * * *

(3) 15 percent of a MIPS eligible clinician's final score for MIPS payment years 2021 and 2022.

■ 43. Section 414.1360 is amended by adding paragraph (a)(2) to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) * * *

(2) *Groups and virtual groups.* Beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.

* * * * *

■ 44. Section 414.1370 is amended by adding paragraph (e)(2) and revising paragraph (g)(1) to read as follows:

§ 414.1370 APM scoring standard under MIPS.

* * * * *

(e) * * *

(2) For purposes of calculating the APM Entity group score under the APM scoring standard, MIPS scores submitted by virtual groups will not be included.

* * * * *

(g) * * *

(1) *Quality.* Beginning in the 2020 Performance year—

(i) *MIPS APMs that require APM Entities to submit quality data through a MIPS submission mechanism.* The MIPS quality performance category score for a performance period will be calculated for the APM Entity using the data submitted for the APM Entity through a MIPS submission mechanism in accordance with § 414.1335.

(ii) *MIPS APMs that do not require APM Entities to submit quality data through a MIPS submission mechanism.* The APM Entity will be assigned an APM Quality Reporting Credit worth 50 percent of the total quality performance category score. The APM Quality Reporting Credit will be added to the MIPS quality performance category score to generate an APM Entity quality performance category score, which in no case shall exceed 100. The MIPS quality performance category score for a performance period will be calculated for the APM Entity using the data submitted for the APM Entity through a MIPS submission mechanism in accordance with § 414.1335.

(iii) *Determination of score for each MIPS eligible clinician in an APM entity.* Regardless of whether a MIPS APM requires APM Entities to submit quality data through a MIPS submission mechanism, if data are not submitted for an APM Entity through a MIPS submission mechanism in accordance with § 414.1335, the score for each MIPS eligible clinician in such APM Entity is the higher of either:

(A) A TIN level score based on the measure data for the quality performance category reported by a TIN for the MIPS eligible clinician in accordance with § 414.1335; or

(B) An individual level score based on the measure data for the quality performance category reported by the MIPS eligible clinician in accordance with § 414.1335.

(iv) Quality improvement score. For an APM Entity for which CMS calculated a total quality performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, CMS calculates a quality improvement score for the APM Entity group as specified in § 414.1380(b)(1)(xvi).

* * * * *

■ 45. Section 414.1380 is amended—

■ a. In paragraph (b)(1)(i) introductory text by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ b. In paragraph (b)(1)(i)(A)(*1*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ c. By revising paragraph (b)(1)(ii) introductory text;

■ d. By adding paragraph (b)(1)(ii)(C);

■ e. By revising paragraph (b)(1)(v)(A)(*1*)(*i*);

■ f. In paragraph (b)(1)(v)(A)(*1*)(*ii*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ g. In paragraph (b)(1)(v)(B)(*1*)(*i*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ h. In paragraph (b)(1)(vi)(C)(*4*) by removing the phrase ''2020 and 2021 MIPS payment year'' and adding in its place the phrase ''2020 through 2022 MIPS payment years'';

■ i. By revising paragraph (b)(3)(ii)(A) and (C);

■ j. In paragraph (c)(2)(i)(A)(*4*) by removing the phrase ''beginning with the 2021 MIPS payment year'' and adding in its place the phrase ''for the 2021 and 2022 MIPS payment years'';

■ k. In paragraph (c)(2)(i)(A)(*5*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019, 2020, 2021, and 2022'';

■ l. By adding paragraph (c)(2)(i)(A)(*9*);

■ m. By revising paragraph (c)(2)(i)(C) introductory text;

■ n. By adding paragraphs (c)(2)(i)(C)(*10*) and (c)(2)(ii)(D);

■ o. By revising paragraph (c)(2)(iii) and (c)(3) introductory text; and

■ p. In paragraph (e)(2)(i)(C) by removing the phrase ''Can be attributed'' and adding in its place the phrase ''Can be assigned''.

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(ii) *Benchmarks.* Except as provided in paragraphs (b)(1)(ii)(B) and (C) of this section, benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

* * * * *

(C) Beginning with the 2022 MIPS payment year, for each measure that has a benchmark that CMS determines may have the potential to result in inappropriate treatment, CMS will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology at paragraph (b)(1)(ii) of this section.

* * * * *

(v) * * *

(A) * * *

(*1*) * * *

(*i*) Each high priority measure must meet the case minimum requirement at paragraph (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero.

* * * * *

(3) * * *

(ii) * * *

(A) The practice has received accreditation from an accreditation organization that is nationally recognized.

* * * * *

(C) The practice is a comparable specialty practice that has received recognition through a specialty recognition program offered through a nationally recognized accreditation organization; or

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*9*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

* * * * *

(C) Under section 1848(o)(2)(D) of the Act, a significant hardship exception or other type of exception is granted to a MIPS eligible clinician based on the following circumstances for the Promoting Interoperability performance category. Except as provided in paragraph (c)(2)(i)(C)(10) of this section, in the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(10) Beginning with the 2020 MIPS payment year, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

* * * * *

(ii) * * *

(D) For the 2022 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
No Cost	55	0	15	30
No Promoting Interoperability	70	15	15	0
No Quality	0	15	15	70
No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	85	15	0	0
No Quality and no Improvement Activities	0	15	0	85

(iii) For the Promoting Interoperability performance category to be reweighted in accordance with paragraph (c)(2)(ii) of this section for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting based on the circumstances described in paragraph (c)(2)(i) of this section, or the group or virtual group must meet the definition of a hospital-based MIPS eligible clinician or a non-patient facing MIPS eligible clinician as defined in § 414.1305.

(3) *Complex patient bonus.* For the 2020, 2021 and 2022 MIPS payment years, provided that a MIPS eligible clinician, group, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as follows:

* * * * *

■ 46. Section 414.1385 is amended by revising paragraph (a) to read as follows:

§ 414.1385 Targeted review and review limitations.

(a) *Targeted review.* A MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year. The process for targeted review is as follows:

(1) A MIPS eligible clinician or group (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review.

(2) All requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors for the MIPS payment year. The targeted review request submission period may be extended as specified by CMS.

(3) A request for a targeted review may be denied if the request is duplicative of another request for a targeted review; the request is not

submitted during the targeted review request submission period; or the request is outside of the scope of the targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician or group for a year. If the targeted review request is denied, there will be no change to the MIPS final score or associated MIPS payment adjustment factors for the MIPS eligible clinician or group. If the targeted review request is approved, the MIPS final score and associated MIPS payment adjustment factors may be revised, if applicable, for the MIPS eligible clinician or group.

(4) CMS will respond to each request for a targeted review timely submitted and determine whether a targeted review is warranted.

(5) A request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician or group that is the subject of a request for a targeted review, it must be provided and received by CMS within 30 days of CMS' request. Non-responsiveness to CMS' request for additional information may result in a final decision based on the information available, although another non-duplicative request for a targeted review may be submitted before the end of the targeted review request submission period.

(6) If a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician or group with regard to measures, activities, performance categories, and the final score, as well as the MIPS payment adjustment factors.

(7) Decisions based on the targeted review are final, and there is no further review or appeal. CMS will notify the individual or entity that submitted the request for a targeted review of the final decision.

(8) Documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period.

* * * * *

■ 47. Section 414.1395 is amended by revising paragraph (a) to read as follows:

§ 414.1395 Public reporting.

(a) *General.* (1) CMS posts on Physician Compare, in an easily understandable format, the following:

(i) Information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and

(ii) The names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs.

(2) CMS periodically posts on Physician Compare aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category.

(3) The information made available under this section will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

* * * * *

■ 48. Section 414.1400 is amended by—

■ a. Revising paragraphs (a)(2) introductory text and (a)(2)(iii);

■ b. Adding paragraphs (a)(4)(v) and (vi);

■ c. Revising paragraph (b)(1);

■ d. Adding paragraphs (b)(2)(iii), (b)(3)(iv) through (vii), ;

■ e. Revising paragraph (c)(1);

■ f. Adding paragraphs (c)(2)(i) and (ii); and

■ g. Revising paragraphs (f)(1) introductory text and (f)(3) introductory text.

The revision and addition reads as follows:

§ 414.1400 Third party intermediaries.

(a) * * *

(2) Beginning with the 2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the following MIPS performance categories, and Health IT vendors must be able to submit data for at least one of the following MIPS performance categories:

* * * * *

(iii) Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or § 414.1380(c)(2)(i)(C)(*1*) through (*7*) or § 414.1380(c)(2)(i)(C)(*9*)).

* * * * *

(4) * * *

(v) The third party intermediary must provide services throughout the entire performance period and applicable data submission period.

(vi) Prior to discontinuing services to any MIPS eligible clinician, group, or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan.

* * * * *

(b) * * *

(1) *QCDR self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a QCDR must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing QCDRs that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period. Beginning with the 2023 payment year, QCDRs are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at paragraph (b)(2)(iv) of this section), and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Each QCDR would still be required to submit notification to CMS within the reporting period promptly within the month of realization of the impending deficiency in order to be considered for this exception, as discussed at paragraph (b)(2)(iv) of this section.

(2) * * *

(iii) Beginning with the 2023 MIPS payment year, require QCDRs to provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR. Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period.

(3) * * *

(iv) QCDR measure considerations for approval include:

(A) Preference for measures that are outcome-based rather than clinical process measures.

(B) Measures that address patient safety and adverse events.

(C) Measures that identify appropriate use of diagnosis and therapeutics.

(D) Measures that address the domain of care coordination.

(E) Measures that address the domain for patient and caregiver experience.

(F) Measures that address efficiency, cost, and resource use.

(G) Beginning with the 2021 performance period—

(*1*) That QCDRs link their QCDR measures as feasible to at least one of the following at the time of self-nomination:

(*i*) Cost measure;

(*ii*) Improvement activity; or

(*iii*) An MVP.

(*2*) In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations.

(H) Beginning with the 2020 performance period CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

(I) We give greater consideration to measures for which QCDRs:

(*1*) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and

(*2*) Utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development.

(J) Beginning with the 2020 performance period, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved.

(*1*) Beginning with the 2020 performance period, in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.

(*2*) [Reserved]

(v) QCDR measure requirements for approval include:

(A) QCDR Measures that are beyond the measure concept phase of development.

(B) QCDR Measures that address significant variation in performance.

(C) Beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

(D) Beginning with the 2021 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

(E) Beginning with the 2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. If the QCDR measures are not harmonized, CMS may reject the duplicative QCDR measure.

(vi) Beginning with the 2021 performance period, QCDR measures may be approved for 2 years, at CMS discretion, by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke QCDR measure second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; requires QCDR measure harmonization; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

(vii) Beginning with the 2020 performance period, QCDR measure rejection criteria considerations include, but are not limited to, the following factors:

(A) QCDR measures that are duplicative, or identical to other QCDR measures or MIPS quality measures that are currently in the program.

(B) QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.

(C) QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.

(D) QCDR measures that meet the topped out definition as described at § 414.1305.

(E) QCDR measures that are process-based, with consideration to whether the removal of the process measure impacts the number of measures available for a specific specialty.

(F) Whether the QCDR measure has potential unintended consequences to a patient's care.

(G) Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.

(H) Whether the previously identified areas of duplication have been addressed as requested.

(I) QCDR measures that split a single clinical practice or action into several QCDR measures.

(J) QCDR measures that are ''check-box'' with no actionable quality action.

(K) QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years.

(L) Whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality actions, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.

(M) QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician.

(N) QCDR measures that focus on rare events or ''never events'' in the measurement period.

(c) * * *

(1) *Qualified registry self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a qualified registry must self-nominate from September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional

information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period. Beginning with the 2023 payment year, qualified registries are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(c)(2)(ii)), and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Each qualified registry would still be required to submit notification to CMS within the reporting period promptly within the month of realization of the impending deficiency in order to be considered for this exception, as discussed at § 414.1400(c)(2)(ii).

(2) * * *

(i) Beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) Beginning with the 2023 MIPS payment year, require qualified registries to provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registries. Exceptions to this requirement may occur if the qualified registries does not receive the data from their clinician until the end of the performance period.

* * * * *

(f) * * *

(1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, has submitted a false certification under paragraph (a)(5) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

* * * * *

(3) For purposes of paragraph (f) of this section, CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, including but not limited to, if the submitted data:

* * * * *

■ 49. Section 414.1405 is amended by—

■ a. Adding paragraphs (b)(7) and (8);

■ b. Adding paragraph, (d)(6); and

■ c. Revising paragraph (f) introductory text.

The additions and revision read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(7) The performance threshold for the 2022 MIPS payment year is 45 points.

(8) The performance threshold for the 2023 MIPS payment year is 60 points.

* * * * *

(d) * * *

(6) The additional performance threshold for the 2022 and 2023 MIPS payment years is 85 points.

* * * * *

(f) *Exception to application of MIPS payment adjustment factors to model-specific payments under section 1115A APMs.* Beginning with the 2019 MIPS payment year, the payment adjustment factors specified under paragraph (e) of this section are not applicable to payments that meet all of the following conditions:

* * * * *

■ 50. Section 414.1415 is amended by revising paragraph (c)(5) and (6) to read as follows:

§ 414.1415 Advanced APM criteria.

* * * * *

(c) * * *

(5) For the purposes of this section, expected expenditures means the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the terms of the APM should not exceed the Medicare Part A and Part B expenditures for a participant in the absence of the APM. If the expected expenditures under the APM exceed the Medicare Part A and Part B expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for purposes of Advanced APM determinations.

(6) *Capitation.* A full capitation arrangement meets this Advanced APM criterion. For purposes of this part, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. Arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program (part 422 of this title) are not considered capitation arrangements for purposes of this paragraph (c)(6).

* * * * *

■ 51. Section 414.1420 is amended by revising paragraph (d)(2) introductory text, (d)(2)(ii), (d)(3)(ii)), (d)(4) introductory text and (d)(5) through (8) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(d) * * *

(2) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model financial risk standard.* The APM Entity participates in a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, does one or more of the following:

* * * * *

(ii) Require direct payment by the APM Entity to the payer;

* * * * *

(3) * * *

(ii) Except for risk arrangements described under paragraph (d)(2) of this section, the risk arrangement must have a marginal risk rate of at least 30 percent.

(4) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model nominal amount standard.* For a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model to meet the Medicaid Medical Home Model nominal amount standard, the total annual amount that an APM Entity potentially owes a payer or forgoes must be at least the following amounts:

* * * * *

(5) *Marginal risk rate.* For purposes of this section, the marginal risk rate is defined as the percentage of actual expenditures that exceed expected expenditures for which an APM Entity is responsible under an other payer payment arrangement.

(i) In the event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of this section, with exceptions for large losses as described in paragraph (d)(5)(ii) of this section and small losses

as described in paragraph (d)(5)(iii) of this section.

(ii) *Allowance for large losses.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments under the other payer payment arrangement greater than or equal to the total risk requirement under paragraph (d)(3)(i) of this section.

(iii) *Allowance for minimum loss rate.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by less than 4 percent of expected expenditures.

(6) *Expected expenditures.* For the purposes of this section, expected expenditures is defined as the Other Payer APM benchmark. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Other Payer Advanced APM determinations, the expected expenditures under the payment arrangement should not exceed the expenditures for a participant in the absence of the payment arrangement. If expected expenditures under the payment arrangement exceed the expenditures that the participant would be expected to incur in the absence of the payment arrangement, such excess expenditures are not considered when assessing financial risk under the payment arrangement for Other Payer Advanced APM determinations.

(7) *Capitation.* A full capitation arrangement meets this Other Payer Advanced APM criterion. For purposes of paragraph (d)(3) of this section, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the payment arrangement for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed for the purposes of reconciling or sharing losses incurred or savings earned by the participant. Arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program (part 422 of this title) are not considered capitation arrangements for purposes of this paragraph.

(8) *Aligned Other Payer Medical Home Model and Medicaid Medical Home Model 50 eligible clinician limit.* Notwithstanding paragraphs (d)(2) and (4) of this section, if an APM Entity participating in an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model is owned and operated by an organization with 50 or more eligible clinicians whose Medicare billing rights have been reassigned to the TIN(s) of the organization(s) or any of the organization's subsidiary entities, the requirements of paragraphs (d)(1) and (3) of this section apply.

* * * * *

■ 52. Section 414.1425 is amended by revising paragraphs (c)(5) and (6), and (d)(3) and (4) to read as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(c) * * *

(5) Beginning in the 2020 QP Performance Period, an eligible clinician in an APM Entity is not a QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that QP performance period under the terms of the Advanced APM, even if such termination date occurs within such QP Performance Period.

(6) Beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities.

* * * * *

(d) * * *

(3) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that performance period under the terms of the Advanced APM.

(4) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTING

■ 53. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 54. Section 415.172 is amended by revising the section heading and paragraph (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

* * * * *

(b) *Documentation.* Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures

and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

* * * * *

■ 55. Section 415.174 is amended by—

■ a. Revising paragraph (a)(6); and

■ b. Removing and reserving paragraph (b).

The revision reads as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) * * *

(6) The medical records must document the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary. The extent of the teaching physician's participation may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter to each beneficiary in accordance with the documentation requirements at § 415.172(b).

(b) [Reserved]

PART 416—AMBULATORY SURGICAL CENTERS

■ 56. The authority citation for part 416 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 57. Section 416.42 is amended by revising paragraph (a)(1) to read as follows:

§ 416.42 Condition for coverage—Surgical services.

* * * * *

(a) * * *

(1) Immediately before surgery—

(i) A physician must examine the patient to evaluate the risk of the procedure to be performed; and

(ii) A physician or anesthetist as defined at § 410.69(b) of this chapter must examine the patient to evaluate the risk of anesthesia.

* * * * *

PART 418—HOSPICE CARE

■ 58. The authority citation for part 418 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 59. Section 418.106 is amended by revising paragraph (b)(1) to read as follows:

§ 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

* * * * *

(b) * * *

(1) Drugs may be ordered by any of the following practitioners:

(i) A physician as defined by section 1861(r)(1) of the Act.

(ii) A nurse practitioner in accordance with state scope of practice requirements.

(iii) A physician assistant in accordance with state scope of practice requirements and hospice policy who is:

(A) The patient's attending physician; and

(B) Not an employee of or under arrangement with the hospice.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 60. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 61. Section 424.67 is added to subpart E to read as follows:

§ 424.67 Enrollment requirements for opioid treatment programs (OTP).

(a) *General enrollment requirement.* In order for a program or eligible professional (as that term is defined in section 1848(k)(3)(B) of the Act) to receive Medicare payment for the provision of opioid use disorder treatment services, the provider must qualify as an OTP (as that term is defined in § 8.2 of this title) and enroll in the Medicare program under the provisions of this section and of subpart P of this part.

(b) *Specific requirements and standards for enrollment.* To enroll in the Medicare program, an OTP must meet all of the following requirements and standards:

(1) Fully complete and submit the Form CMS–855B application (or its successor application) and any applicable supplement or attachment thereto to its applicable Medicare contractor. This includes, but is not limited to, the following:

(i) Maintain and submit to CMS (via the applicable supplement or attachment) a list of all physicians, other eligible professionals, and pharmacists (regardless of whether the individual is a W–2 employee of the OTP) who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP. The list must include the physician's, other eligible professional's, or pharmacist's:

(A) First and last name, and middle initial.

(B) Social Security Number.

(C) National Provider Identifier.

(D) License number (if applicable).

(ii) Certifying via the Form CMS–855B and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in paragraphs (b) and (d) of this section.

(2) Comply with the application fee requirements in § 424.514.

(3) Successfully complete the assigned categorical risk level screening required under, as applicable, § 424.518(b) and (c).

(4)(i) Have a current, valid certification by SAMHSA for an opioid treatment program consistent with the provisions and requirements of § 8.11 of this title.

(ii) A provisional certification under § 8.11(e) of this title does not meet the requirements of paragraph (b)(4)(i) of this section.

(5) Report on the Form CMS–855B and/or any applicable supplement all OTP staff who meet the definition of ''managing employee'' in § 424.502. Such individuals include, but are not limited to, the following:

(i) Medical director (as described in § 8.2 of this title).

(ii) Program sponsor (as described in § 8.2 of this title).

(6)(i)(A) Must not employ or contract with a prescribing or ordering physician or eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries based on the same categories of detrimental felonies, as well as case by case detrimental determinations, found at § 424.535(a)(3).

(B) Paragraph (b)(6)(i)(A) of this section applies regardless of whether the individual in question is:

(*1*) Currently dispensing narcotics at or on behalf of the OTP; or

(*2*) A W–2 employee of the OTP.

(ii) Must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who is revoked from Medicare under § 424.535 or any other applicable section in Title 42, or who is on the preclusion list under § 422.222 or § 423.120(c)(6) of this chapter.

(iii) Must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who has a prior adverse action by a State oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. CMS will consider the factors enumerated at § 424.535(a)(22) in each

case of patient harm that potentially applies to this paragraph.

(7)(i) Sign (and adhere to the term of) a provider agreement in accordance with the provisions of part 489 of this chapter.

(ii) An OTP's appeals under part 498 of a Medicare revocation (under § 424.535) and a provider agreement termination (under § 489.53 of this chapter) must be filed jointly and, as applicable, considered jointly by CMS under part 498 of this chapter.

(8) Comply with all other applicable requirements for enrollment specified in this section and in subpart P of this part.

(c) *Denial of enrollment.* CMS may deny an OTP's enrollment application on any of the following grounds:

(1)(i) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) of this section or fails to meet any other applicable requirement in this section.

(ii) Any of the denial reasons in § 424.530 applies.

(2) An OTP may appeal the denial of its enrollment application under part 498 of this chapter.

(d) *Continued compliance, standards, and reasons for revocation.* (1) Upon and after enrollment, an OTP—

(i) Must remain validly certified by SAMHSA as required under § 8.11 of this title.

(ii) Remains subject to, and must remain in full compliance with, the provisions of this section and of subpart P of this part. This includes, but is not limited to, the provisions of paragraph (b)(6) of this section, the revalidation provisions in § 424.515, and the deactivation and reactivation provisions in § 424.540.

(iii) Upon revalidation, successfully complete the moderate categorical risk level screening required under § 424.518(b).

(2) CMS may revoke an OTP's enrollment on any of the following grounds:

(i) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) or fails to meet any other applicable requirement or standard in this section, including, but not limited to, the OTP standards in paragraphs (b)(6) and (d)(1) of this section.

(ii) Any of the revocation reasons in § 424.535 applies.

(3) An OTP may appeal the revocation of its enrollment under part 498 of this title.

(e) *Claim payment.* For an OTP to receive payment for furnished drugs:

(1) The prescribing or medication ordering physician's or other eligible professional's National Provider Identifier must be listed on Field 17 of the Form CMS–1500; and

(2) All other applicable requirements of this section, this part, and part 8 of this title must be met.

(f) *Relation to part 8 of this title.* Nothing in this section shall be construed as:

(1) Supplanting any of the provisions in part 8 of this title; or

(2) Eliminating an OTP's obligation to maintain compliance with all applicable provisions in part 8 of this title.

■ 62. Section 424.502 is amended by adding the definition of ''State oversight board'' in alphabetical order to read as follows:

§ 424.502 Definitions.

* * * * *

State oversight board means, for purposes of §§ 424.530(a)(15) and 424.535(a)(22) only, any State administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the State.

* * * * *

■ 63. Section 424.518 is amended by adding paragraphs (b)(1)(xii) and (xiii) and (c)(1)(iv) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(b) * * *

(1) * * *

(xii) Prospective (newly enrolling) opioid treatment programs that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since October 23, 2018.

(xiii) Revalidating opioid treatment programs.

* * * * *

(c) * * *

(1) * * *

(iv) Prospective (newly enrolling) opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018.

* * * * *

■ 64. Section 424.520 is amended by revising paragraph (d) introductory text to read as follows:

§ 424.520 Effective date of Medicare billing privileges.

* * * * *

(d) *Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs.* The effective date for billing privileges for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs is the later of—

* * * * *

■ 65. Section 424.521 is amended by revising the section heading and paragraph (a) introductory text to read as follows:

§ 424.521 Request for payment by physicians, non-physician practitioners, physician and non-physician organizations, ambulance suppliers, and opioid treatment programs.

(a) Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs may retrospectively bill for services when the physician, non-physician practitioner, physician or non-physician organization, ambulance supplier, or opioid treatment program has met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to—

* * * * *

■ 66. Section 424.530 is amended by adding paragraph (a)(15) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(15) *Patient harm.* (i) The physician or other eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a denial is appropriate, CMS considers the following factors:

(A) The nature of the patient harm.

(B) The nature of the physician's or other eligible professional's conduct.

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a State oversight board, IRO, Federal or State health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(*1*) License restriction(s) pertaining to certain procedures or practices.

(2) Required compliance appearances before State oversight board members.

(*3*) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(*4*) Administrative/monetary penalties.

(*5*) Formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.

(ii) Paragraph (a)(15)(i) of this section does not apply to actions or orders pertaining exclusively to either of the following:

(A) Required participation in rehabilitation or mental/behavioral health programs; or

(B) Required abstinence from drugs or alcohol and random drug testing.

* * * * *

■ 67. Section 424.535 is amended by—

■ a. In paragraph (a)(14) introductory text, by removing the phrase ''prescribing Part D drugs'' and adding in its place the phrase ''prescribing Part B or D drugs''; and

■ b. Adding paragraph (a)(22).

The addition reads as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(22) *Patient harm.* (i) The physician or other eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation is appropriate, CMS considers the following factors:

(A) The nature of the patient harm.

(B) The nature of the physician's or other eligible professional's conduct.

(C) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by the State oversight board, IRO, Federal or State health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(*1*) License restriction(s) pertaining to certain procedures or practices.

(*2*) Required compliance appearances before State medical board members.

(*3*) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(*4*) Administrative or monetary penalties.

(*5*) Formal reprimand(s).

(D) If applicable, the nature of the IRO determination(s).

(E) The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.

(ii) Paragraph (a)(22)(i) of this section does not apply to actions or orders pertaining exclusively to either of the following:

(A) Required participation in rehabilitation or mental/behavioral health programs; or

(B) Required abstinence from drugs or alcohol and random drug testing.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 68. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

§ 425.612 [Amended]

■ 69. Section 425.612 is amended in paragraph (a)(1)(v)(E) introductory text by removing the phrase ''paragraph (a)(1)(v)(B)'' and adding in its place the phrase ''paragraph (a)(1)(v)(D)''.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 70. The authority citation for part 489 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

■ 71. Section 489.2 is amended by adding paragraphs (b)(10) and (c)(3) to read as follows:

§ 489.2 Scope of part.

* * * * *

(b) * * *

(10) Opioid treatment programs (OTPs).

(c) * * *

(3) OTPs may enter into provider agreements only to furnish opioid use disorder treatment services.

■ 72. Section 489.10 is amended by revising paragraph (a) to read as follows:

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter. The RNHCIs must meet the conditions for coverage, conditions for participation and the requirements set forth in this section and elsewhere in this chapter. The OTPs must meet the requirements set forth in this section and elsewhere in this chapter.

* * * * *

■ 73. Section 489.13 is amended by adding paragraph (a)(2)(iii) to read as follows:

§ 489.13 Effective date of agreement or approval.

(a) * * *

(2) * * *

(iii) For an agreement with an opioid treatment program (OTP), the effective date is the effective date of billing as established under § 424.520(d) or § 424.521(a), as applicable.

* * * * *

■ 74. Section 489.53 is amended by revising paragraph (a)(3) to read as follows:

§ 489.53 Termination by CMS.

(a) * * *

(3) It no longer meets the appropriate conditions of participation or requirements (for SNFs and NFs) set forth elsewhere in this chapter. In the case of an RNHCI, it no longer meets the conditions for coverage, conditions of participation and requirements set forth elsewhere in this chapter. In the case of an OTP, it no longer meets the requirements set forth in this section and elsewhere in this chapter.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 75. The authority citation for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7j, and 1395hh.

■ 76. Section 498.2 is amended in the definition of ''Provider'' by revising the introductory text and adding paragraph (3) to read as follows:

§ 498.2 Definitions.

* * * * *

Provider means any of the following:

* * * * *

(3) An entity that has in effect an agreement to participate in Medicare but only to furnish opioid use disorder treatment services.

* * * * *

Dated: October 24, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 28, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix 1: MIPS Quality Measures

Note: Except as otherwise noted in this final rule, previously finalized measures and specialty measure sets will continue to apply for the 2022 MIPS payment year and future years. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table A as follows: NQF #/eCQM NQF #.

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TABLE Group A: New Quality Measures Finalized for the 2022 MIPS Payment Year and Future Years

A.1 International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	476
Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Measure Steward:	Large Urology Group Practice Association and Oregon Urology Institute
Numerator:	Patients with a documented improvement of at least 3 points in their urinary symptom score during the measurement period.
Denominator:	Equals Initial Population. Initial population is: Male patients with an initial diagnosis of benign prostatic hyperplasia, 6 months prior to, or during the measurement period, and a urinary symptom score assessment within 1 month of initial diagnosis and a follow-up urinary symptom score assessment within 6-12 months, who had a qualifying visit during the measurement period.
Exclusions:	Denominator: Patients with urinary retention that starts within 1 year of initial BPH diagnosis; Patients with an initial BPH diagnosis that starts during, or within 30 days of hospitalization; Patients with a diagnosis of morbid obesity, or with a BMI Exam >40 before the follow up urinary symptom score.
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	eCQM Specifications
Rationale:	This measure was proposed because it represents a patient reported outcome by evaluating the patient's response regarding their symptoms associated with the diagnosis of Benign Prostatic Hyperplasia (BPH). Results can be used by clinicians in evaluating whether the patient's symptoms from BPH have improved during the 6 to 12 months after diagnosis and treatment of this disease. The measure was evaluated by the MAP and it was conditionally supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. Measure information provided by the measure developer indicates IPSS and AUA-SI are statistically valid and reliable symptom scores. The IPSS was adopted by the World Health Organization in 1993. The AUA-SI was developed and validated by the American Urological Association in 1992. The IPSS uses the same questions as the AUA-SI, but also adds a disease-specific quality of life question (OLeary, 2005). It is a reproducible, validated index designed to determine disease severity and response to therapy (DSilva, 2014). Based on the information provided by the measures steward, we believe the measure is evidence-based and represents an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.
Comment: One commenter had concerns about the proposed International Prostate Symptom Score (IPSS) or American Urological Association – Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia measure. The commenter noted that this measure was conditionally recommended by the MAP for inclusion in a federal program pending a full evaluation by NQF as there were concerns regarding the feasibility of the measure collection. Specifically, there were concerns about the measure's ability to feasibly obtain response rates electronically or in a clinical setting. While the developer indicated that the measure was tested using multiple EHR formats, MAP members indicated that additional testing with multiple EHRs should be completed. While the commenter supported patient reported outcome measures, it recommended against including this new measure in the MIPS program until there is a full evaluation and recommendation by the NQF. **Response:** We thank the commenter for their comment and agree that NQF endorsement is preferred; however, it is not required for implementation into MIPS. The measure steward completed additional testing following NQF feedback regarding their submission to NQF for the Fall 2018 review. After completing this testing, the measure steward found that it is feasible to obtain response rates electronically. The CMS document "Blueprint for the CMS Measures Management System v.15.0", explains software resources such as "Bonnie that allow eCQM developers to test and verify the behavior of their	

Category	Description
eCQM logic. The Bonnie application allows measure developers to independently load measures that they have constructed using the Measure Authoring Tool (MAT) and helps measure developers execute the measure logic against the constructed patient test deck and evaluate whether the logic aligns with the intent of the measure." After consideration of the comments, we are finalizing the *International Prostate Symptom Score (IPSS) or American Urological Association Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia* measure as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

A.2. Multimodal Pain Management

Category	Description
NQF #: / eCQM NQF #:	N/A
Quality #:	477
Description:	Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.
Measure Steward:	American Society of Anesthesiologists (ASA)
Numerator:	Patients for whom multimodal pain management is administered in the perioperative period from 6 hours prior to anesthesia start time until discharged from the post-anesthesia care unit.
Denominator:	Patients, aged 18 years and older, who undergo selected surgical procedures
Exclusions:	Emergent Cases
Measure Type:	Process
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes (Opioid-related)
Collection Type:	MIPS CQMs Specifications
Rationale:	This measure was proposed because it encourages clinicians to effectively manage patients' pain using multimodal strategies, which in turn can significantly reduce unnecessary opioid use, excessive post-operative prescriptions, and length of stay. We believe there is an urgent need for measures that address the opioid epidemic affecting the nation. It is imperative to include measures in MIPS that support healthy outcomes for patients using opioids. The clinical action being evaluated within this measure supports the reduction in use of opioids for patients in the perioperative treatment of pain. The measure was updated from what was submitted to the MAP following feedback from stakeholders and NCQA's Technical Expert Panel (TEP). The original measure evaluated by the MAP was conditionally supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. The measure steward indicated that testing data from 503 clinicians for 24,728 cases met the denominator criteria during testing of the measure. The mean performance rate calculated from this data was 74.24 percent with a standard deviation of +/- 0.1492 with a performance range of 0.00 to 100.00. Reliability was assessed at the clinician level and based on data from a large, academic medical center and a Veterans Health Administration facility. In May 2018, the ASA conducted a systematic assessment of face validity among members of its Committee on Pain Medicine and Committee on Regional Anesthesia and Acute Pain Medicine. The 33 respondents indicated a substantial level of agreement supporting this measure's value and validity. Based on the information provided by the measures steward, we believe the measure is evidence-based and represents an important clinical process. The measure steward revised the measure by adding an age criteria and removing elective cases as an inclusion criteria. Upon stakeholder feedback, the denominator eligible cases were expanded to make the measure more applicable to ambulatory settings. Due to this denominator expansion, an age of 18 years and older was added to the denominator criteria as many of the pediatric cases captured by the expanded codes do not require multimodal pain management. Additionally, pediatric patients have a different range of appropriate multimodal pain management options. As such, the measure steward limited the patient population to the clinically relevant adult patient population. A denominator exclusion was added for emergent cases to replace the previous elective surgery requirement for denominator eligibility. The measure steward also stated, citing user feedback, when emergent cases are an exclusion criterion compared to using elective cases as an inclusion criterion, the measure produced more reliable results. We agree that these changes result in a more clinically relevant, reliable, and meaningful measure by expanding the denominator eligible code set to capture all applicable adult patients in different settings and refining the patient population to be in alignment with these changes. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.
Comment: Several commenters supported the new Multimodal Pain Management measure. The measure aligns with the meaningful measures initiative as it seeks to manage postoperative pain through multimodal pain strategies instead of using just opioids. However, the commenter stated there is considerable room for improvement based on preliminary measure performance data. The measure would serve as a meaningful indicator of quality and limit a critical access point for opioid use, abuse, or dependence while effectively managing pain. Another commenter thanked CMS for adding this high priority measure, as multimodal pain management is an essential element of Enhanced Recovery After Surgery (ERAS). **Response:** We thank the commenters and appreciate their support of new measure Q477. We agree the measure would limit a critical access point for opioid use, abuse, or dependence while still effectively managing pain. We agree with the commenter in reference to the considerable room for improvement in performance of treating patients 6 hours prior to anesthesia start time until discharged from the post-anesthesia care unit. The Multimodal Pain Management quality measure was previously available as a Quality Clinical Data Registry (QCDR) measure under the Anesthesia Quality Institute, National Anesthesia Clinical Outcomes Registry QCDR and has produced data to support that there is room for improvement in the performance for this particular interaction between anesthesiologist and patients. The 2018 performance data also supported a clinical need to promote multimodal pain management prior to the use of opioids. We believe this measure will support eligible clinicians to use alternative pain therapies. After consideration of the comments, we are finalizing the *Multimodal Pain Management* measure as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

A.3. Adult Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	N/A
Description:	Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Measure Steward:	National Committee for Quality Assurance
Numerator:	Numerator 1: Members in Denominator 1 (D1) who received an influenza vaccine on or between July 1 of the year prior to the measurement period and June 30 of the measurement period. Numerator 2: Members in D2 who received at least 1 Td vaccine or 1 Tdap vaccine between 9 years prior to the start of the measurement period and the end of the measurement period. Numerator 3: Members in D3 who received at least 1 dose of the herpes zoster live vaccine or 2 doses of the herpes zoster recombinant vaccine anytime on or after the members 50th birthday. Numerator 4: Members in D4 who were administered both the 13-valent pneumococcal conjugate vaccine and the 23-valent pneumococcal polysaccharide vaccine at least 12 months apart, with the first occurrence after the age of 60. Numerator 5: The actual number of required immunizations administered to members in D5.
Denominator:	Denominator 1: Members age 19 and older at the start of the measurement period. Denominator 2: Members age 19 and older at the start of the measurement period. Denominator 3: Members age 50 and older at the start of the measurement period. Denominator 4: Members age 66 and older at the start of the measurement period. Denominator 5: The total number of possible immunizations required for members age 19 and older determined by their age at the start of the measurement period.
Exclusions:	Denominator: Members with any of the following: • Prior anaphylactic reaction to the vaccine or its components any time during or before the measurement period. • History of encephalopathy within seven days after a previous dose of a Td-containing vaccine. • Active chemotherapy during the measurement period. • Bone marrow transplant during the measurement period. • History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & HB-S disease or cerebrospinal fluid leaks any time during the member's history prior to or during the measurement period. • In hospice or using hospice services during the measurement period.
Measure Type:	Process
Measure Domain:	Community/Population Health (section 1848(s)(1)(B)(v)of the Act)
High priority measure:	No
Collection Type:	MIPS CQMs Specifications, CMS Web Interface Measure Specifications
Rationale:	We proposed this preventive immunization measure because it is a comprehensive evaluation for compliance with recommended adult vaccinations and supports the 2019 adult immunization schedule that has been approved by the CDC, which is based on the recommendation from the Advisory Committee on Immunization Practices. NCQA and the HHS National Vaccine Program Office submitted this measure via Call for Measures to be considered for MIPS implementation. This robust composite measure assesses the quality clinical action regarding the administration of the influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. This measure is consistent with Healthy People 2020 goals, developed by the Centers for Disease Control and Prevention, to promote healthy behaviors, for increasing immunization rates. The measure was evaluated by the MAP, but this entity did not support this composite measure since it had not been analytically tested at the clinician level, but clinically it is evidence-based as required by section 1848(q)(2)(D)(v) of the Act. We believe that the health plan level version of the measure can be adapted to the clinician level by revising the measure analytics to assess the proportion of patients who have been administered influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines by MIPS eligible clinicians. Implementing the measure at the clinician level does not change the medical intent or evidence supporting preventive immunizations for patients. Therefore, we believe implementing the measure at the clinician level will be successful. Currently, MIPS includes three of the four composite measure's components as individual measure analytics. Individual measures: Q110: Preventive Care and Screening: Influenza Immunization; and Q111: Pneumococcal Vaccination Status for Older Adults have been implemented in the MIPS and PQRS programs for a combined total of over seven years. Another component of this composite measure, Q474: Zoster (Shingles) Vaccination, was implemented as a new individual measure in 2019 MIPS and was tested at the clinician and group level prior to submission to the Call for Measures. The administration of the vaccination diphtheria toxoids and acellular pertussis (Tdap), contained in Adult Immunization Status, is also present in the MIPS program as a component within measure Q394: Immunizations for Adolescents. We recognize this measure is specified currently for adolescents, but believe the logic this measure represents is adaptable to the adult population.

Category	Description
	We believe that the individual measures referenced above represent each component of the Adult Immunization Status composite measure. Additionally, measures Q110 and Q111 have been successfully implemented in all MIPS collection types. This accomplishment supports the face validity of these measure concepts and demonstrates the ease in which the composite health plan measure can be adapted for MIPS use. As such, we believe the health plan level version of this measure can be adapted accordingly to suit the program requirements of MIPS. Nonetheless, we will continue to work with the measure steward to obtain additional testing results regarding this composite measure's implementation for programs beyond the health plan level. The measure steward provided the following health plan evidence to support the value of proposing this composite measure as a quality measure. The information is based on commercial and Medicaid plan performance rates for members aged 19-64 and Medicare plan rates for members aged 65 and older. Across the plans, performance rates were as follows: influenza (mean=24 percent, min=3 percent, max=73 percent; Td or Tdap (mean=35 percent, min=1 percent, max=94 percent); zoster (mean=28 percent, min=0.1 percent, max=85 percent); pneumococcal (mean=17 percent, min=1 percent, max=62 percent); and composite (mean=28 percent, min=2 percent, max=79 percent). We believe this evidence represents there is a need to improve adult vaccination coverage. Based on the information provided by CDC in conjunction with the ACIP, we believe the measure is clinically evidence-based and represents an important clinical process Therefore, we maintain that this measure provides a comprehensive assessment of quality adult preventive care and would met the meaningful measure initiative. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

Comment: Several commenters opposed the addition of the new Adult Immunization Status measure that would result in the removal of measures Q110: Preventive Care and Screening: Influenza Immunization, Q111: Pneumococcal Vaccination Status for Older Adults, and Q474: Zoster (Shingles) Vaccination. Commenters were concerned with the complexity of this new measure and the confusion it could bring to clinicians. Benchmarks published by CMS for measures Q110 and Q111 still show a significant gap in care that can be addressed by these measures. Q474 is a newer measure, and there may be a benchmark published based on retroactive performance at a later date. Several commenters expressed concern that the new measure was not supported by the MAP, had only been tested at the health plan level, and that measure specifications had not yet been released.

One commenter opposed the new Adult Immunization Status measure in MIPS and the Web Interface because the look-back period for some of these immunizations of 10 years is not captured in the EHRs for patients that are new to a practice or where the EHR has changed. There are other barriers to Medicare beneficiaries receiving recommended immunizations, including in states with high levels of poverty, due to high cost-sharing for beneficiaries. Most vaccines are given at pharmacies or hospitals, so communication with the primary care physician is sporadic, resulting in higher burden to primary care physicians.

Another commenter did not support the new measure because it does not aid surgical teams in providing improved surgical care and it adds an unnecessary task to a surgeon's workflow that provides little value to surgical patients. Another commenter was concerned with replacing measure Q110 with an untested composite immunization measure that could prevent CMS from understanding how many patients with heart failure are receiving this potentially lifesaving immunization.

Another commenter stated they believed that the Adult Immunization Status measure should also reflect the evaluation/assessment need to update the patient's measles, mumps, and rubella (MMR) immunization status. Another commenter stated the new measure requires multiple age-appropriate preventive immunizations and provided suggestions to improve the applicable numerators and denominators for the measure.

Response: We thank the commenters for their comments. We are not finalizing the Adult Immunization Status measure for the 2020 MIPS performance period/2022 MIPS payment year due to the imminent changes in clinical guidelines for pneumococcal vaccination. We believe it is advantageous to evaluate the clinical guidelines and Adult Immunization Status measure for inclusion through future rulemaking. This assures alignment between this important clinical measure and the clinical guidelines that support it.

We appreciate the comments regarding EHRs and the eCQMs that support those systems and will continue to encourage measure stewards to develop eCQMs in the future. We agree that with the 10-year look-back period allowed for some of these immunizations, they may not have been captured in the EHR at the time of administration, or for patients that are new to a practice or where the EHR has changed. However, we believe the data from EHRs and state immunization registries should be updated and reflect the immunization status for every patient to maintain accurate and current medical record documentation. In response to the opposition of this measure citing the popularity and preference of the individual measures for individual performance rates, we believe this measure will continue to support endeavors for thorough administration of each vaccination as applicable to the eligible clinicians' patient population. We believe that submitting one vaccination measure would be less burdensome than potentially submitting several vaccination measures. The measure is specified to provide eligible clinicians' performance rates for each immunization and would be benchmarked based on the overall compliance. This would allow eligible clinicians to review and identify deficits in administration of vaccinations and make adjustments to their practice accordingly to drive and support public health initiatives.

Category	Description
	We agree this measure may not add value to the overall interaction or care a surgeon may provide to a patient especially since primary care eligible clinicians most likely represent the front-line preventive care for this clinical concept. We encourage the surgeons to collaborate and develop measures that offer quality outcomes within their specialty while decreasing burden to their workflow. We encourage the commenters to collaborate with the measure steward, NCQA, for potential measure revisions that may lead to quality outcomes for patients. In regards to the suggestions to improve the applicable numerators and denominators for the measure, we encourage the commenter to collaborate with the measure steward to revise the measure for possible implementation in MIPS in future years. After consideration of the comments, we are not finalizing the *Adult Immunization Status* measure as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years. Upon further discussion with PPRNet, the current measure steward of measure Q474, they have decided to no longer maintain the measure within MIPS and do not plan to transfer stewardship of the measure to CMS. As a result, measures Q110 and Q111, are being retained in the MIPS program and Q474 is being removed.

A.4. Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	478
Description:	This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Numerator:	The proportion of a provider's (clinic's or clinician's) patient care episodes that met or exceeded the risk-adjusted predicted Residual Change Score. The Residual Change Score is defined as the difference between the Actual and Predicted Change Scores where: 1. The Actual Score is the patient's Functional Status (FS) Score; 2. The Actual Change Score is the change in the patient's FS score from Admission to Discharge; and 3. The Predicted Change Score is the risk-adjusted prediction of FS change. (Please see the Comments section of JIRA submission for details of the Risk-adjustment component.) Calculating the Residual Change Score, Example: • Actual Score at Admission = 45 • Actual Score at Discharge = 60 o Actual Change Score (Discharge minus Admission) = +15 o Predicted Change Score = +10 • Residual Change Score (Actual Change minus Predicted) = +5 Numerator Options: • Performance Met = The Residual Change Score is equal to or greater than 0 • Performance Not Met = The Residual Change Score is less than 0 Performance may be calculated on 3 levels as follows: 1. Patient Level: For the individual patient episode, the patient's Actual FS scores relative to the risk-adjusted predicted. This level should be used for optimizing care as described below.* 2. Clinician Level: The average of the Residuals for patient care episodes managed by a clinician (individual provider) over a 12 month time period. 3. Clinic Level: The average of the Residuals for patient care episodes managed by a group of clinicians within a clinic over a 12 month time period. * A provider's (clinician's or clinic's) performance must be assessed based on an average all of the provider's patient episodes. On the level of the individual patient, variation is expected. When an individual episode does not result in meeting or exceeding the performance standard, the functional data should be useful to the provider in optimizing the balance of effectiveness/efficiency for that particular care episode. For example, if patient-perceived function is not improving, or has plateaued in progress, that data may be a component of provider-patient communication and care decision-making such as the following examples: 1. Does the provider understand the patient's perception of his/her current level of function? 2. Should the treatment plan be modified? 3. Should the patient be discharged sooner than later? 4. Should the patient be referred to a different care provider?
Denominator:	Patients aged 14+ who initiated rehabilitation therapy, chiropractic, or medical episodes of care for neck impairments including but not limited to cervical (neck) pain, radiculopathy, strain, sprain, stenosis, myelopathy, spondylosis or disc disorders.
Exclusions:	None
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High priority measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications

Category	Description
Rationale:	We proposed this measure because neck pain is prevalent, impacts functional ability and productivity, and is costly. Measurement results can be used by clinicians in evaluating whether the patient's functional status has improved with initiation of rehabilitation therapy. The measure was evaluated by the MAP conditionally and it was supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required in section 1848(q)(2)(D)(v) of the Act. The measure steward indicated that this measure offers ample room for improvement for performance based on testing data. The results from testing were that for 1378 clinics, 24.24 percent were classified as low performers, 60.01 percent as average, and 15.75 percent as high. The measure steward believed and we agree that having only 15.75 percent classified as high leaves more than adequate room for improvement in eligible clinician performance over time. Based on the information provided by the measures steward, we believe this measure is evidence-based and represents an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

Comment: One commenter supported new measure Q478: Functional Status Change for Patients with Neck Impairments that will serve as a replacement to measure Q223: Functional Status Change for Patients with General Orthopedic Impairments. The new neck-specific measure was developed in response to feedback that providers and patients desired measures specific to neck impairments and had increasingly found the functional questions in the general orthopedic measures to be less meaningful. The addition of this new neck-specific measure will result in a comprehensive set of measures to support the most common orthopedic-type conditions seen by physical and occupational therapists, physicians, and chiropractors. The commenter supported CMS' recognition of patient reported outcome measures (PROMs) within the Quality Payment Program.

The commenter indicated that measure Q478, as submitted to the MUC, contained Exclusions and Exceptions that were not included in the version published in the proposed rule for measures Q217 through Q222 (84 FR 41207 through 41218). As a result, the commenter requested that the following (which is not identical to what was submitted to the MUC) be included in the measure adopted by the final rule in order to provide specific and separate clinically logical reasons for excepting or excluding patient episodes and to bring this measure into alignment with measures Q217 through Q222:

DENOMINATOR EXCLUSIONS

- Documentation stating patient has a diagnosis of a degenerative neurological condition such as ALS, MS, or Parkinson's diagnosed at any time before or during the episode of care.
- Patient unable to complete the Neck Functional Status PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available.

DENOMINATOR EXCEPTIONS

- Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only).
- Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery or hospitalized.
- Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown).
- Patient refused to participate.

Response: We agree with the comment that measure Q478 should be aligned as submitted to the MUC. We are finalizing the Denominator Exclusions as represented on the MUC List to read: Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care; and Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only), which matches what was indicated on the MUC. We are finalizing the Denominator Exceptions as represented on the MUC List to read: Patient refused to participate at admission and/or discharge. Patient unable to complete the Neck FS PROM at admission or discharge due to cognitive deficit, visual deficit, motor deficit, language barrier, or low reading level, and a suitable proxy/recorder is not available. Patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown) - Medical reasons (e.g., scheduled for surgery or hospitalized).

After consideration of the comments, we are finalizing the *Functional Status Change for Patients with Neck Impairments* measure with modifications for the 2020 MIPS performance period/2022 MIPS payment year and future years.

TABLE Group AA: New Quality Measure Finalized for the 2023 MIPS Payment Year and Future Years

In addition to the new quality measures in Table Group A, we proposed to add one administrative claims based quality measure for the 2023 MIPS payment year and future years. Quality measures that are specified through the administrative claims collection type do not require separate data submission to CMS. Administrative claims measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims. We proposed to add this administrative claims-based measure beginning with the 2023 MIPS payment year to allow for time to further refine the measure analytics prior to implementation within the program.

AA.1. All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions

Category	Description
NQF # / eCQM NQF #:	TBD
Quality #:	TBD
Description:	Risk-adjusted outcome measure that uses the outcome of acute, unplanned admissions (per 100 person-years at risk of admission) to assess care quality. Includes Medicare fee-for-service beneficiaries aged 65 years or older who have two or more of the following nine chronic conditions: (1) acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia, (3) atrial fibrillation, (4) chronic kidney disease, (5) chronic obstructive pulmonary disease or asthma, (6) depression, (7) diabetes, (8) heart failure, and (9) stroke or transient ischemic attack. The measure adjusts for: • Demographic variables, clinical comorbidities, and measures of frailty/disability. • Two social risk factors: (1) The Agency for Healthcare Research and Quality Socioeconomic Status Index (AHRQ SES Index) and (2) density of physician specialists. The AHRQ SES Index is a widely used and validated measure of area deprivation derived from the American Community Survey (ACS) census block group-level data and linked to a patient's ZIP code. It summarizes SES measures of employment, income, education, and housing.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Risk-standardized acute admissions per 100 person-years at risk for admission
Denominator:	Medicare fee-for-service beneficiaries ≥ 65 years of age with ≥ 2 of 9 chronic conditions: (1) Acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia (3) Atrial fibrillation (4) Chronic kidney disease (5) Chronic obstructive pulmonary disease or asthma (6) Depression (7) Diabetes (8) Heart failure (9) Stroke or transient ischemic attack
Exclusions:	Denominator Exclusions: (1) Patients without continuous enrollment in Medicare Part A or Part B during the measurement period. (2) Patient was in hospice at any time during the year prior to the measurement year or at start of the measurement year. (3) Patient had no Evaluation and Management visit to a MIPS eligible clinician. Numerator Exclusions: (1) Planned admissions (2) Other admissions that likely do not reflect the quality of ambulatory chronic disease management and primary care provided by the included eligible clinicians: • Complications of procedures or surgeries • Accidents • Injuries • Admissions directly from a skilled nursing facility or acute rehabilitation facility • Admissions that occur within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility • Admissions that occur while patients are enrolled in Medicare's hospice benefit
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes (Outcome)
Collection Type:	Administrative Claims
Rationale:	We proposed this risk-adjusted administrative claims measure to assess Medicare aged > 65 patients who have two or more of the following nine chronic conditions: (1) acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia, (3) atrial fibrillation, (4) chronic kidney disease, (5) chronic obstructive pulmonary disease or asthma, (6) depression, (7) diabetes, (8) heart failure, and (9) stroke or transient ischemic attack. More than two-thirds of Medicare beneficiaries have been diagnosed with or treated for two or more chronic conditions. People with multiple chronic conditions (MCCs) are more likely to be admitted to the hospital than those without chronic conditions or with a single chronic condition. Additionally, they are more likely to visit the emergency department, use post-acute care (such as skilled nursing facilities), and require home health assistance based on the CMS Chronic Conditions among Medicare Beneficiaries Chartbook: 2012 Edition (cited in ACO 38 measure information form). This measure promotes improved MCC management and coordinated care by assessing the unplanned hospital admissions for this high-risk population. The measure is specified through the administrative claims collection type that does not require separate data submission to CMS. This administrative claims measure is

Category	Description
	calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims as well as hospital inpatient, outpatient, and physician claims for clinical risk adjustment. It uses the outcome of acute, unplanned admissions (per 100 person-years at risk of admission) to assess care quality. This measure is added for the 2023 MIPS payment year to allow time to work through operational factors of implementing the measures.

Comment: One commenter urged CMS not to finalize the addition of the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure for the MIPS program until it has been reviewed and recommended by both the MAP Coordinating Committee and the NQF. In addition, the commenter indicated that some of the nine chronic conditions included in the measure description--(1) acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia, (3) atrial fibrillation, (4) chronic kidney disease, (5) chronic obstructive pulmonary disease or asthma, (6) depression, (7) diabetes, (8) heart failure, and (9) stroke or transient ischemic attack--are not actually chronic conditions. The commenter noted, for example, that acute myocardial infarction, is, by definition, acute and therefore not chronic.

Several other commenters opposed the addition of this measure and the move to adopt global and population health administrative claims measures in MIPS. As discussed in comments related to MVPs, these types of measures do not result in meaningful or actionable feedback for specialists, require a large sample to produce reliable results, and do not provide a complete picture of quality due to the limitations of claims data.

Several commenters had concerns with measure attribution at the individual level for this measure, as many unplanned readmissions are outside of the individual clinician's control. Commenters believed this measures is primary-care based, and the attribution methodology holds physicians responsible for care they did not provide. If CMS moves forward with implementation in 2021, commenters requested that CMS ensure this measure is adequately risk-adjusted, reviewed by the MAP, and reviewed for reliability. Also, commenters requested that the results of validity testing be publicly disseminated and reviewed by the NQF prior to implementation. Another commenter stated it may be more appropriate for CMS to pursue more targeted measures that focus on ambulatory-sensitive admissions, in order to hone in on variation in care that can be tied to clinician performance.

Several commenters supported the addition of this measure to MIPS.

Response: We thank the commenters for their comments. We agree that NQF endorsement of measures is preferred, however, an NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required in section 1848(q)(2)(D)(v) of the Act.

Although we acknowledge that acute myocardial infarction is not a chronic condition, this diagnosis has a high correlation with coronary heart disease, which represents a chronic condition. The inclusion of this diagnosis will be reviewed, but maintain that it is appropriate to include. According to the Centers for Disease Control (CDC), coronary heart disease (CHD) is the most common type of heart disease, killing over 370,000 people annually. In addition, the CDC states that every year about 735,000 Americans have a heart attack. Of these, 525,000 are a first heart attack and 210,000 happen in people who have already had a heart attack (https://www.cdc.gov/heartdisease/facts.htm). Given the amount of resources that are allocated to patients with these conditions and the frequency at which heart attacks occur, we believe that it is important to include acute myocardial infarction in this measure in order to address its impact on unplanned hospital admission.

We believe that population measures may reduce burden on clinicians and allow for assessment of public health issues on a larger scale. We believe this measure gives valuable data for practices of 16 or more clinicians who meet the case minimum of 200. Reliability is one of the many important and scientific issues that we address and tests during our measure development process regardless of measure type (that is, whether the measures are population-based or provider-specific measures). This requirement ensures a large sample to produce reliable results and a complete picture of quality interactions between eligible clinicians and patients within Medicare Part B Claims data. As such, this perspective assesses the overall effective clinical care of patients with multiple chronic conditions (MCC) within this group of clinician's interaction with patients. The measure would work to promote improvements in MCC management and care coordination by assessing this high-risk population's rate of unplanned hospital admissions. In order to decrease clinician burden, the measure uses administrative claims data, which does not require separate data submission. The measure ensures adequate attribution to those eligible clinicians that are specifically treating multiple chronic conditions by requiring at least two of the nine chronic conditions presence on the claim form to be considered in the denominator sample.

One commenter indicated that the measure could result in unintended consequences, including increasing the risk that providers avoid admitting patients with multiple chronic conditions to the hospital for medically necessary care. We believe that eligible clinicians will treat patients ethically, ensure a patient's safety, and support positive patient outcomes. We believe this measure encourages eligible clinicians to actively seek innovation in the treatment of patient with multiple chronic conditions to avoid costly hospital admissions.

After consideration of the comments and because we value stakeholder feedback, we are not finalizing the *All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions* measure as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. This action will allow additional time for the MAP process to occur and to obtain expert feedback prior to implementation. In addition, this will allow time to take all of the commenters' concerns into consideration in the event we propose this measure in future rulemaking.

TABLE Group B: New Specialty Measures Sets and Modifications to Previously Finalized Specialty Measure Sets Finalized for the 2022 MIPS Payment Year and Future Years

We proposed to add seven new specialty measures sets: Endocrinology, Nutrition/Dietician, Pulmonology, Chiropractic Medicine, Clinical Social Work, Audiology, and Speech Language Pathology. These sets were proposed to be added based in part on the expanded definition of the MIPS eligible clinician for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals. In addition, we have received stakeholder feedback requesting additional specialty sets for clinician types whom did not have an existing specialty measures set. We solicited comment on applicable measures for a Clinical Social Work specialty set in the event clinical social workers were proposed for inclusion in the definition of a MIPS eligible clinician in future rulemaking. We also proposed to modify the previously finalized specialty measures sets below based upon review of updates made to existing quality measure specifications, proposed the addition of new measures for inclusion in MIPS, and considered the feedback provided by specialty societies. In the first column, existing measures with substantive changes described in Table Group D are noted with an asterisk (*), existing measures with substantive changes for the 2019 MIPS performance period described in Table Group DD are noted with a double asterisk (**), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to fully represent the regulatory definition of high priority measures. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table B as follows: NQF # / eCQM NQF #.

NOTE:

- In the instance a title and/or measure description had a substantive change finalized in Table Group D, the revised title and/or measure description is reflected in the specialty measure sets located in Table Group B.
- Under Table Group B, we respond to comments that are related to new measures that were proposed for addition to measure sets, and measures that were proposed for removal. Any comments received on previously finalized measures are out of scope and not included in this final rule.
- Measures that were not finalized for removal in this final rule have been added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for their retention is addressed under Table Group C.

The definition of high priority at § 414.1305 includes an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

The following specialty measure set was excluded from this group because we did not propose any changes to this specialty measure set: Interventional Radiology. Therefore, we refer readers to the CY 2018 Quality Payment Program final rule for the previously finalized Interventional Radiology specialty measure set (82 FR 54098 through 54099).

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ALLERGY/IMMUNOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	160	CMS52v8	eCQM Specifications	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis	Health Resources and Services Administration	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale. In addition, we proposed to remove this measure from the specialty set because it is not applicable to this specialty as Allergy/Immunology specialists do not diagnose, treat or manage HIV/AIDS patients.
After consideration of the comments, we are finalizing the removal of measures from the *Allergy/Immunology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0236	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	2726	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Outcome)	N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	2681	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A	463	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists

B.2. Anesthesiology

MEASURES FINALIZED FOR **ADDITION** TO THE ANESTHESIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Opioid)	N/A	477	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Multimodal Pain Management**: Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists	This measure was proposed as a new measure for the 2020 performance period. We proposed to include this measure in the Anesthesiology specialty set as it is clinically relevant to this clinician type.
Comment: One commenter was supportive of adding the new Multimodal Pain Management measure to the Anesthesiology set. Detailed comments from this commenter were included in Table A for this measure. **Response:** We thank the commenter for supporting the addition of this new measure to the Anesthesiology set. After consideration of the comments, we are finalizing the measures for addition to the *Anesthesiology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.									

B.3a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	National Committee for Quality Assurance

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Efficiency)	N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology Foundation
! (Efficiency)	N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology Foundation
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	438	CMS347 v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And □ Most recent tobacco status is Tobacco Free -- And □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And □ Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE CARDIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Cardiology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.3b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Electrophysiology Cardiac Specialist measure set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.3b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	348	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.	American College of Cardiology Foundation
* ! (Outcome)	2474	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
* ! (Outcome)	N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.4. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Gastroenterological Association
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A	425	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
ndicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Efficiency)	N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	American Gastroenterological Association

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE GASTROENTEROLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	271	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients regardless of age with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. Individuals who received an assessment for bone loss during the year prior and current year are considered adequately screened to prevent overuse of X-ray assessment	American Gastroenterological Association	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	343	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate**: The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.	American Society for Gastrointestinal Endoscopy	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Gastroenterology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.5. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.5. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
* ** §	0028 / 0028e	226	CMS13 8v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Foundation (PCPI®)

B.5. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A	317	CMS22 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
*	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician- or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment	American Academy of Dermatology
* ! (Care Coordination)	N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist	American Academy of Dermatology

B.6. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	009	CMS128 v8	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
§ * ! (Appropriate Use)	N/A	066	CMS146v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0104e	107	CMS161v8	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0034 / N/A	113	CMS130 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
* ! (Opioid)	N/A	305	CMS137 v8	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A	309	CMS124 v8	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139 v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ) Centers for Medicare & Medicaid Services
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* ! (Outcome)	0209	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710 / 0710e	370	CMS159 v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A	377	CMS90v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	1407	394	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	438	CMS347 v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND □ Most recent tobacco status is Tobacco Free -- AND □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND □ Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§ ! (Appropriate Use)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* ! (Appropriate Use)	N/A	472	CMS249 v2	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349 v2	eCQM Specifications	Process	Community /Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.6. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure was proposed for inclusion into the Family Medicine specialty set as a replacement for measure Q109: Osteoarthritis (OA): Function and Pain Assessment, which was proposed for removal. Measure Q182 includes the patient population in measure Q109, but is more robust in that it requires more frequent assessment and a plan of care.

Comment: One commenter opposed the addition of the new Adult Immunization Status measure to the Family Medicine set. Detailed comments were included in the comments under this measure in Table A. Generally, the commenter stated that the new measure carries too high of a burden to primary care physicians, and the measure has not yet been tested at the clinician level.

Response: We thank the commenter for their comment. We have decided not to finalize the addition of the new Adult Immunization Status measure. We disagree that this measure carries a higher burden as it combines components of previously implemented measures within the Family Medicine set. Please see Table A.3 for the complete rationale.

Comment: One commenter opposed the addition of measure Q182: Functional Outcome Assessment to the Family Medicine set because of the frequency requirement of every visit or every 30 days for all patients over age 18. Doing a functional assessment at this frequency for all patients seen by family physicians, particularly healthy patients, is burdensome, wasteful, and detracts from meaningful care needed by patients during a visit. The measure requires a more targeted denominator that will benefit from functional assessment. At the most recent meeting of the CQMC, stakeholders opposed measure Q182 for these reasons.

Response: We thank the commenter for their comment, however, the Family Medicine set contains 68 quality measures and eligible clinicians may choose not to submit measure Q182.

After consideration of the comments, we are finalizing the measures for addition to the *Family Medicine Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE FAMILY MEDICINE SET Note: In this this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0712e	371	CMS160v 8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	PPRNet	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Family Medicine Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.7. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	009	CMS12 8v8	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery
*	0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults**: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0421 / 0421e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS13 8v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS16 5v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Opioid)	N/A	305	CMS13 7v8	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. □ Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. □ Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
§	N/A	309	CMS12 4v8	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
*	N/A	317	CMS22 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology
! (Appropria te Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
* ! (Appropria te Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
! (Appropria te Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* ! (Outcome)	0209	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A	377	CMS90v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastro-enterological Association
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	438	CMS347v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND □ Most recent tobacco status is Tobacco Free -- AND □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND □ Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	NA	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* ! (Appropriate Use)	N/A	472	CMS249v2	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
u*	N/A	475	CMS349v2	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INTERNAL MEDICINE SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0712e	371	CMS160v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	PPRNet	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the removal of measures from the *Internal Medicine Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.8. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.8. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A	066	CMS146 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis**: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0104e	107	CMS161 v8	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
	N/A	254	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.8. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
* ! (Efficiency)	N/A	415	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A	416	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.8. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE EMERGENCY MEDICINE SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	255	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).	American College of Emergency Physicians	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

Comment: One commenter opposed the removal of measure Q091 from the Emergency Medicine set. The commenter understood CMS' rationale for removing the measure because it is clinical equivalent to measure Q093: Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use. However, the commenter believed that for emergency physicians, measure Q091 remains the more meaningful measure for emergency medicine physicians.

Response: We thank the commenters for their comment. In the circumstance an eligible clinician does not prescribe and antibiotic, most likely a topical therapy would be prescribed. However, the eligible clinician is able to prescribe both an antibiotic and topical therapy and remain numerator compliant for this measure. Despite their limited utility, about 20-40 percent of patients with AOE receive oral antibiotics, often in addition to topical therapy (Rosenfeld, et al., 2014). We encourage the commenter to collaborate with the measure steward to develop a measure that promotes the use of antibiotic alternatives while decreasing inappropriate antibiotic usage, and submit to the Call for Measures once tested at the clinician level.

After consideration of the comments, we are finalizing the removal of measures from the *Emergency Medicine Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.9. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement
*	N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2372 / N/A	112	CMS125 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
§	N/A	309	CMS124 v8	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
§	N/A	310	CMS153 v8	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v 8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture	National Committee for Quality Assurance
! (Patient Safety)	2063	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A	472	CMS249 v2	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349 v2	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.9. Obstetrics/Gynecology

MEASURES FINALIZED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type and drives quality of care by assessing the rate of elective deliveries before 39 weeks gestation in the absence of medical indication, following The American College of Obstetrics and Gynecology clinical guidance.
* ! (Care Coordination)	N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth and who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type.

Comment: One commenter noted the inclusion of the proposed Adult Immunization Status measure under the Obstetrics/Gynecology set. The commenter encouraged CMS to also consider adopting the Prenatal Immunization Status measure, which was created specifically for maternal populations and better reflects the Advisory Committee on Immunization Practices (ACIP) recommendations for pregnant women, specifically Tdap and influenza. Like the Adult Immunization Status measure, the Prenatal Immunization Status measure will help to address substantial disparities in prenatal immunization rates. Getting a flu shot reduces a pregnant woman's risk of hospitalization by 40 percent and helps protect the newborn before he/she is old enough to be vaccinated.

Response: The Adult Immunization Status measure is not being finalized at this time. We encourage the commenter to collaborate with the measure steward of the Prenatal Immunization Status measure to submit to the Call for Measures for consideration for inclusion in MIPS.

After consideration of the comments, we are finalizing the measures for addition to the *Obstetrics/Gynecology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per American College of Obstetrics and Gynecology (ACOG), American Urogynecologic Society, and American Urological Association guidelines.	American Urogynecologic Society	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
We received no comments on measures proposed for removal impacting this specialty measure set; therefore, we are finalizing the removal of measures from the *Obstetrics/Gynecology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.								

B.10. Ophthalmology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.10. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0086 / 0086e	012	CMS143v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0087	014	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12 month performance period.	American Academy of Ophthalmology
* ! (Care Coordination)	0089 / 0089e	019	CMS142v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0055 / N/A	117	CMS131v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.10. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0563	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12 month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS133v8	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.10. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	303	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome) *	N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.10. Ophthalmology

MEASURES FINALIZED FOR ADDITION TO THE OPHTHALMOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Experience)	N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology	We proposed to include this measure in the Ophthalmology specialty set as it is applicable to this clinician type and drives quality of care by assessing patient satisfaction following cataract surgery.
Comment: One commenter supported the addition of measure Q304: Cataracts: Patient Satisfaction within 90 days Following Cataract Surgery to the Ophthalmology set. The new measure quantifies the percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey. The commenter stated measure Q304 was fairly developed based on stakeholder input and appreciated CMS prioritizing beneficiary satisfaction measures. **Response:** We thank the comment for supporting the addition of measure Q304 to the Ophthalmology set. After consideration of the comments, we are finalizing the measures for addition to the *Ophthalmology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.								

B.10. Ophthalmology

PREVIOSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OPHTHALMOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0564 / 0564e	192	CMS132 v8	eCQM Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures**: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	388	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy):** Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.	American Academy of Ophthalmology	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Ophthalmology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.11. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0421 / 0421e	128	CMS69 v8	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v 9	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* ** §	0028 / 0028e	226	CMS13 8v8	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22 v8	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v8	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period	National Committee for Quality Assurance
! (Care Coordination)	N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	375	CMS66 v8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	376	CMS56 v8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A	470	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement

B.11. Orthopedic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Orthopedic Surgery specialty set as a replacement for measure Q109: Osteoarthritis (OA): Function and Pain Assessment, which is being proposed for removal. Measure Q182 includes the patient population in measure Q109, but is more robust in that it requires more frequent assessment and a plan of care.
* ! (Outcome)	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure was proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.

B.11. Orthopedic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure was proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.
* ! (Outcome)	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure was proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.

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MEASURES FINALIZED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure was proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.
* ! (Outcome)	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure was proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.

B.11. Orthopedic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure was proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.
! (Outcome)	N/A	478	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.	This measure was proposed as a new measure for the 2020 performance period. We proposed to include this measure in the Orthopedic Surgery specialty set as it is clinically relevant to this clinician type.

Comment: Three commenters requested that CMS add measure Q357: Surgical Site Infection (SSI) to Orthopedic Surgery set. This measure currently is assigned as a quality measure in Plastic Surgery, General Surgery, and Otolaryngology sets. In light of the many surgical procedures performed by orthopedic surgeons, it would be appropriate to add this measure to the Orthopedic Surgery set.

Response: We thank the commenters for their comments and would point them to the current posted measure specification as the orthopedic surgeon would not be eligible to submit this measure. The coding contained within the measure's denominator is isolated to general surgery. The measure steward explains that the "risk adjustment is performed with a parsimonious dataset and aims to allow efficient data collection resources and data reporting. Measures have been harmonized when possible." Adding orthopedic surgery procedures to this measure may challenge the inherent risk adjustment. We encourage the commenter to work with the measure steward to include coding within the denominator of measure Q357 that is applicable to the Orthopedic Surgery MIPS eligible clinician, yet maintain the risk adjustment. If measure Q357's denominator is found to support to Orthopedic Surgery, we encourage the commenters to submit their recommendation to the Call for Specialty Measure Set.

After consideration of the comments, we are finalizing the measures for addition to the *Orthopedic Surgery Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0097	046	N/A	Medicare Part B Claim Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	352	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet**: Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	American Association of Hip and Knee Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	353	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.	American Association of Hip and Knee Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Orthopedic Surgery Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.12. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
*	N/A	317	CMS22 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	2803	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Otolaryngology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.13. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.13. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SET								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	1854	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
	1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
! (Care Coordination)	N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.	College of American Pathologists

B.13. Pathology

MEASURES FINALIZED FOR **ADDITION** TO THE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist	American Academy of Dermatology	This measure was proposed for inclusion into the Pathology specialty set as it is applicable to a subset of pathologists and drives care coordination and communication.
We received no comments on the measures proposed for addition to this specialty set. Therefore, we are finalizing the measures for addition to the *Pathology Specialty Measure Set* as indicated for the 2020 MIS performance period/2022 MIPS payment year and future years.									

B.14. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A	066	CMS146v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A	239	CMS155v8	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. □ Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. □ Percentage of patients with counseling for nutrition. □ Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	N/A	240	CMS117v8	eCQM Specifications	Process	Community / Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* ! (Opioid)	N/A	305	CMS137v8	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. □ Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. □ Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
§	N/A	310	CMS153v8	eCQM Specifications	Process	Community / Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	366	CMS136v9	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
*	N/A	379	CMS74v9	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	1365e	382	CMS177v8	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
* §	1407	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	NA	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)

B.14. Pediatrics

MEASURES FINALIZED FOR **ADDITION** TO THE PEDIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0710 / 0710e	370	CMS159 v8	eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement	We proposed to include this measure in the Pediatrics specialty set as the denominator was expanded to include pediatric patients and it drives quality by measuring depression remission.
We received no comments on the measures proposed for addition to this specialty set. Therefore, we are finalizing the measures for addition to the *Pediatrics Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.									

B.14. Pediatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PEDIATRICS SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	160	CMS52v8	eCQM Specifications	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis.	Health Resources and Services Administration	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	467	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Developmental Screening in the First Three Years of Life:** The percentage of children screened for risk of developmental, behavioral and social delays using a standardized screening tool in the 12 months preceding or on their first, second, or third birthday. This is a composite measure of screening in the first three years of life that includes three, age-specific indicators assessing whether children are screened in the 12 months preceding or on their first, second or third birthday.	Oregon Health & Science University	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the removal of measures from the *Pediatrics Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposal for removal from the MIPS program.

Please note, that the proposed rule title for this table should had read "Previously Finalized Measures Proposed for Removal from the Pediatrics Set."

B.15. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421 e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419 e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028 e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PHYSICAL MEDICINE SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the removal of measures from the *Physical Medicine Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.16. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.16. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.16. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.17. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v8	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v 8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	438	CMS347 v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349 v2	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.17. Preventive Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure was proposed for inclusion into the Preventive Medicine specialty set as a replacement for measure Q109: Osteoarthritis (OA): Function and Pain Assessment, which was proposed for removal. Measure Q182 includes the patient population in measure Q109, but is more robust in that it requires more frequent assessment and a plan of care.
We received no comments on the measures proposed for addition to this specialty set. Therefore, we are finalizing the measures for addition to the *Preventive Medicine Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.									

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PREVENTIVE MEDICINE SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	PPRNet	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the removal of measures from the *Preventive Medicine Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

Please note that the proposed rule title for this table should have read "Previously Finalized Measures Proposed for Removal from the Preventive Medicine Set."

B.18. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	268	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
	2872e	281	CMS149 v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Psychiatric Association/ American Academy of Neurology
*	N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.	American Academy of Neurology
	N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction in the past 12 months.	American Academy of Neurology
! (Care Coordination)	N/A	293	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed in the past 12 months	American Academy of Neurology
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
! (Efficiency)	N/A	419	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	435	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Quality Of Life Assessment For Patients With Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12 month measurement period AND whose health related quality of life score stayed the same or improved.	American Academy of Neurology

B.19. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Mental/Behavioral Health specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	009	CMS128 v8	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
*	0104e	107	CMS161 v8	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/P opulation Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	2872e	281	CMS149 v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Psychiatric Association/ American Academy of Neurology

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	N/A	366	CMS136v9	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	1365e	382	CMS177v8	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: ● The percentage of discharges for which the patient received follow-up within 30 days after discharge. ● The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
	2803	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	325	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition.	American Psychiatric Association	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0712e	371	CMS160v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table for rationale.
0711	411	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Six Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission six months (+/- 60 days) after an index event date.	Minnesota Community Measurement	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the measures for removal from the *Mental/Behavioral Health Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.20. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.20. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
! (Efficiency)	0508	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms:** Percentage of final reports for screening mammograms that are classified as "probably benign".	American College of Radiology
! (Care Coordination)	N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
	0507	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology
! (Care Coordination)	0509	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology
! (Appropriate Use)	N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology

B.20. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology
* ! (Appropriate Use)	N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* *(Bosniak I or II)*. • Adrenal lesion less than or equal to 1.0 cm. • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols.	American College of Radiology
! (Appropriate Use)	N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

B.20. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE DIAGNOSTIC RADIOLOGY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	361	N/A	MIPS CQMs Specifications	Structure	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are submitted to a radiation dose index registry that is capable of collecting at a minimum selected data elements.	American College of Radiology	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	362	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12 month period after the study.	American College of Radiology	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

Comment: One commenter opposed the removal of four radiology measures from the Diagnostic Radiology set: measures Q146, Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms, Q225, Radiology: Reminder System for Screening Mammograms, Q361, Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry, and Q362, Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes.

Response: Please see our detailed response under Table C for the decision to retain measures Q146 and 225 and finalize removal of measures Q361 and Q362.

After consideration of the comments, we are finalizing the removal of measures from the *Diagnostic Radiology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.21. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement
*	N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEPHROLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure was proposed for removal beginning with 2022 MIPS Payment Year. See Table C for rationale.
1667	328	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	330	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter.	Renal Physicians Association	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	403	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end -stage renal disease (ESRD) who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care.	Renal Physicians Association	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:**	PPRNet	This measure was proposed for removal beginning with the 2022

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEPHROLOGY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.		MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the removal of measures from the *Nephrology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.22. General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421 e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419 e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI)
	N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.22. General Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE GENERAL SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	354	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons	We proposed to include this measure in the General Surgery specialty set as it is clinically relevant to this clinician type.

Comment: One commenter generally supported the addition of measure Q354: Anastomotic Leak Intervention to the General Surgery set, as it a foundational conformance measure that identifies adverse events for the specified procedures and provides relevant and actionable data for surgical practice. However, in order to reliably and validly measure anastomotic leak intervention, the commenter said a single source to collect, analyze, and aggregate data is needed.

The commenter has found that measuring the same quality measure, with the same measure specification across registries, does not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation, including the lack of standardized data definitions, lack of standardized risk adjustment/data analytics, inconsistency of data ascertainment methods, and lack of common normalization methods.

Response: We thank the commenter for supporting the addition of measure Q354 to the General Surgery set. We require measures to be submitted as specified for MIPS and clinicians should not use specifications from other programs to ensure that performance can be assessed across MIPS eligible clinicians. In addition, Qualified Registries and QCDRs are required to perform data validation execution reports to ensure accurate benchmarking. We believe that the measure specification, which contains specific coding to define the sample population and the measure flow that outlines the systemic approach to align patients into the appropriate numerator options, supports standardized implementation of the measure concept regardless of the data source.

After consideration of the comments, we are finalizing the measures for addition to the *General Surgery Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GENERAL SURGERY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the removal of measures from the *General Surgery Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.23. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons
! (Outcome)	N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A	420	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND □ Most recent tobacco status is Tobacco Free -- AND □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND □ Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE VASCULAR SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive**: Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1534	347	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Are Discharged Alive**: Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale
1523	417	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive**: Percentage of patients undergoing open repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Vascular Surgery Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.24. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0129	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	0114	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§! (Outcome)	0119	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE THORACIC SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0130	165	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0131	166	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Thoracic Surgery Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.25. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0390	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
*	N/A	462	CMS645 v3	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.25. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	476	CMS771 v1	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) change 6-12 months after diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association Symptom Index (AUA-SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	This measure was proposed as a new measure for the 2020 performance period. We proposed to include this measure in the Urology specialty set as it is clinically relevant to this clinician type.
We received no comments on the measures proposed for addition to this specialty set. Therefore, we are finalizing the measures for addition to the *Urology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.									

B.25. Urology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE UROLOGY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence**: Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per American College of Obstetrics and Gynecology (ACOG), American Urogynecologic Society, and American Urological Association guidelines	American Urogynecologic Society	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the removal of measures from the *Urology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.26a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The Oncology specialty set has been updated to include Hematology and has been renamed as Oncology/Hematology. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157v8	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Appropriate Use)	1858	450	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy:** Percentage of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab.	American Society of Clinical Oncology
§	1859	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	1860	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A	462	CMS645v3	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.26a. Oncology/Hematology

MEASURES FINALIZED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	067	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.	American Society of Hematology	We proposed to include this measure in the Oncology/Hematology specialty set as this set was updated to include Hematology for the 2020 performance period and this measure is clinically relevant.
	N/A	069	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period.	American Society of Hematology	We proposed to include this measure in the Oncology/Hematology specialty set as this set was updated to include Hematology for the 2020 performance period and this measure is clinically relevant.
	N/A	070	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry**: Percentage of patients aged 18 years and older, seen within a 12-month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Oncology/Hematology specialty set as this set was updated to include Hematology for the 2020 performance period and this measure is clinically relevant.

Comment: One commenter did not support the addition of measure Q069: Hematology: Multiple Myeloma: Treatment with Bisphosphonates to the Oncology/Hematology set until further review by the measure steward. The commenter stated that the two bisphosphonate drugs listed in the specifications are pamidronate and zoledronate. However, patients are being treated with the drug denosumab and should not be counted as non-concordant for this measure. Not only is denosumab FDA-approved for this indication, it is also considered an alternative to pamidronate and zoledronic acid in the NCCN and ASCO guidelines. Therefore, the commenter recommended that before inclusion of measure Q069 in the Oncology/Hematology measure set, the measure steward should review current guidelines and consider editing the numerator criteria so that a patient receiving pamidronate, zoledronic acid, or denosumab be considered concordant with the measure.

One commenter thanked CMS for the proposed additions to the Oncology/Hematology set and encouraged finalization of this measure set.

Response: We thank the commenter for their comment and agree that it is important to allow eligible clinicians and patients to utilize shared decision making when determining what treatment to administer as denosumab has been clinically indicated in the treatment of bone problems in patients with multiple myeloma that is not in remission. We have collaborated with the measure steward and agree that in the clinical situation in which denosumab is indicated and administered to the patient that eligible clinicians may submit a medical reason or patient reason exception when clinically applicable and documented in the patient's medical chart.

After consideration of the comments, we are finalizing the measures for addition to the *Oncology/Hematology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ONCOLOLGY/HEMATOLOGY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1857	449	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Percentage of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies.	American Society of Clinical Oncology	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	454	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer with more than one emergency department visit in the last 30 days of life.	American Society of Clinical Oncology	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0215	456	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Not Admitted to Hospice (lower score – better):** Percentage of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Zoster (Shingles) Vaccination**: The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination**.**	PPRNet	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the measures for removal from the *Oncology/Hematology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.26b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.26b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology

B.27. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.27. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a	Health Resources and Services Administration

B.27. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							minimum of 60 days between medical visits.	
*	N/A	475	CMS349 v2	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.27. Infectious Disease

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE INFECTIOUS DISEASE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	407	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. Nafcillin, Oxacillin or Cefazolin) as definitive therapy.	Infectious Diseases Society of America	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use**: Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)	We agree with specialty society feedback to remove this measure from this specialty set. Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate testing for children with otitis media with effusion, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Zoster (Shingles) Vaccination**: The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	PPRNet	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Infectious Disease Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.28. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications fo a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated i all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis t be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests t documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE NEUROSURGICAL SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures form the Neurosurgical Specialty Measure Set as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.29. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.29. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.29. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Patient Safety)	0101 / N/A	318	CMS139 v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.30. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.30. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* ! (Patient Safety)	2726	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists

B.30. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.30. Hospitalists

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE HOSPITALISTS SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	407	N/A	Medicare Part B Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. Nafcillin, Oxacillin or Cefazolin) as definitive therapy.	Infectious Diseases Society of America	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Hospitalists Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.31. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.31. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	024	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement
*	N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.31. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology
*	2523	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
*	N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
*	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology

B.31. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v 8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.31. Rheumatology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE RHEUMATOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the removal of measures from the *Rheumatology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.32. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.32. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	378	CMS75v8	eCQM Specifications	Outcome	Community/ Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	379	CMS74v9	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

B.33. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure**	**Indicator**	**Measure Title and Description**	**Measure Steward**
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure**	**Indicator**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure**	**Indicator**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.33. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR ADDITION TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
	0416	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.33. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
	2872e	281	CMS149 v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
*	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.

B.33. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Psychiatric Association/ American Academy of Neurology	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
! (Patient Safety)	0101 / N/A	318	CMS139 v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	We proposed to include this measure into the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
! (Outcome)	N/A	478	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.	This measure was proposed as a new measure for the 2020 performance period. We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.

Comment: One commenter was pleased to see the expansion of the Physical Therapy/Occupational Therapy set they had advocated for during the specialty measure set comment process. This updated measure set will allow these types of providers to more easily navigate and choose measures that are appropriate to their practice.

Response: We thank the commenter for their support on the expansion of this set.

After consideration of the comments, we are finalizing the measures for addition to the *Physical Therapy/Occupational Therapy Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0428	223	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with General Orthopedic Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the measures for removal from the *Physical Therapy/Occupational Therapy Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures were proposed for removal from the MIPS program.								

B.34. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization**: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	2872e	281	CMS14 9v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Psychiatric Association/ American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology

B. 34. Geriatrics

MEASURES FINALIZED FOR **ADDITION** TO THE GERIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older**: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	We proposed to include this measure into the Geriatrics specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We proposed to include this measure into the Geriatrics specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We proposed to include this measure into the Geriatrics specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B. 34. Geriatrics

MEASURES FINALIZED FOR **ADDITION** TO THE GERIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	476	CMS771v1	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) change 6-12 months after diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association Symptom Index (AUA-SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	This measure was proposed as a new measure for the 2020 performance period. We proposed to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type.

Comment: One commenter appreciated the finalization of the Geriatrics set for use in the Quality performance category last year. The commenter encouraged CMS to continue to facilitate and sponsor measure development for the multi-morbid patient with functional impairment who is not institutionalized population. The commenter recommended that CMS prioritize measures that specifically address care of the geriatric population.

The commenter supported the four measures proposed for addition to the Geriatrics set: Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older, Q154: Falls: Risk Assessment, Q155: Falls: Plan of Care, and Q476: International Prostate Symptom Score (IPPS) or American Urological Association Symptom Index (AUA-SI) change 6 – 12 months after diagnosis of Benign Prostatic Hyperplasia.

Response: We appreciate the comment received supporting the additional measures to the Geriatrics set.

After consideration of the comments, we are finalizing the measures for addition to the *Geriatrics Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GERIATRICS SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	PPRNet	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

Comment: One commenter agreed with the removal of Q046 from the Geriatrics set and MIPS altogether. The commenter noted the large caregiver burden associated with this measure may lead to slow or little adoption and the cumbersome specifications will lead to inaccurate data.

Response: We thank the commenter for supporting the removal of measure Q046.

After consideration of the comments, we are finalizing the measures for removal from the *Geriatrics Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures were proposed for removal from the MIPS program.

B.35. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
§ * ! (Appropriate Use)	N/A	066	CMS146 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	2803	402	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE URGENT CARE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
After consideration of the comments, we are finalizing the measures for removal from the *Urgent Care Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.36. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.36. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.36. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology

B.36 Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE SKILLED NURSING FACILITY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	PPRNet	This measure was proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

After consideration of the comments, we are finalizing the measures for removal from the *Skilled Nursing Facility Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.37. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that were proposed for this new measure set.

B.37. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0059 / N/A	001	CMS122v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* §	0055 / N/A	117	CMS131v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0062 / N/A	119	CMS134v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
*	N/A	438	CMS347v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
*	N/A	462	CMS645v3	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute	We proposed to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

Comment: One commenter appreciated a proposed specialty measure set for endocrinology and that its recommended measures were included. A second commenter supported the addition of this set and encouraged CMS to continue exploring new measures focused on diabetes and obesity care.
Response: We thank the commenters for supporting the new Endocrinology set. We encourage the second commenter to collaborate with measure developers to construct new measures focusing on these areas or find existing quality measures outside of MIPS and submit to the Call for Measures for possible inclusion in future years.
After consideration of the comments, we are finalizing the new *Endocrinology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.38. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that were proposed for this new measure set.

B.38. Nutrition/Dietician

MEASURES FINALIZED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.

B.38. Nutrition/Dietician

MEASURES FINALIZED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
§	N/A	239	CMS155 v8	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. □ Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. □ Percentage of patients with counseling for nutrition. □ Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance	We proposed to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.

Comment: Several commenters recommended that CMS adopt four eCQMs as quality measures in MIPS and adopt a specialty measure set for nutrition professionals. These include: NQF #3087/MUC16-294: Completion of a Malnutrition Screening within 24 hours of Admission, NQF #3088/MUC16-296: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening, NQF #3089/MUC16-372: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment, and NQF #3090/MUC16-344: Appropriate Documentation of a Malnutrition Diagnosis. These four measures have been thoroughly evaluated and tested in the hospital setting for inpatients. In addition, one of the commenters has re-specified these four eCQMs for use in the outpatient setting and submitted them for potential use in the MIPS through a qualified clinical data registry for reporting by eligible clinicians in 2020. The commenters recommended CMS include these malnutrition measures in the outpatient setting and to continue exploring new measures focused on diabetes and obesity care.

Response: We thank the commenters for their comment and have finalized the Nutrition/Dietician set. The measures recommended for inclusion within this specialty set are not current or proposed quality measures. Specialty sets are comprised of MIPS quality measures only, and we encourage the commenters to work with the measure stewards of the aforementioned eCQMs for submission to the yearly Call for Measures for consideration of inclusion into MIPS. We encourage the final commenter to collaborate with measure developers to construct new measures focusing on these areas or find existing quality measures outside of MIPS and submit to the Call for Measures for possible inclusion in future years.

After consideration of the comments, we are finalizing the new *Nutrition/Dietician Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.39. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that were proposed for this new measure set.

B.39. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	0102	052	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

MEASURES FINALIZED FOR ADDITION TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	0022 / N/A	238	CMS156v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

Comment: One commenter stated that the Pulmonary set includes measures that address the pharmacologic management of COPD, tobacco screening and cessation intervention, severity assessment of sleep apnea and adherence to positive airway pressure therapy, optimal asthma control and medication management for people with asthma. The commenter concurred with the inclusion of the measures in the Pulmonary set and recommended that CMS add measures to address improvements in quality of life scores and functional capacity for those COPD patients who are enrolled in pulmonary rehabilitation programs.

The commenter requested that two outcomes measures developed by the American Association for Cardiovascular and Pulmonary Rehabilitation (AACVPR) be included in the Pulmonary set: NQF measure #0770: Percentage of patients with COPD enrolled in pulmonary rehabilitation (PR) who are found to increase their health-related quality of life score (HRQQL) and NQF measure #0701: Percentage of patients with COPD who are enrolled in pulmonary rehabilitation (PR) who are found to increase their functional capacity by at least 25 meters (82 feet), as measured by a standardized 6-minute walk test (6MWT).

The commenter also supported the inclusion of measure Q052: Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy in the Pulmonology set and requested that measure Q051: Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation be added if not finalized for removal.

Response: We thank the commenter for supporting the addition of measure Q052 to the Pulmonology set. As discussed under Table C, we are finalizing removal of measure Q051 from MIPS. We note that there is no NQF #0770 currently available. There is an NQF #0700: Health-related Quality of Life in COPD patients before and after Pulmonary Rehabilitation if that is the measure the commenter was referring to. We encourage the commenter to collaborate with the measure steward(s) of the AACVPR COPD measures to submit them to the Call for Measures, if fully tested at the clinician level.

Comment: One commenter supported the addition of measures Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis and Q279: Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy to the Pulmonology set.

Response: We thank the commenter supporting the addition of measures Q277 and Q279 to the Pulmonology set.

After consideration of the comments, we are finalizing the new *Pulmonology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.40. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that were proposed for this new measure set.

B.40. Chiropractic Medicine

MEASURES FINALIZED FOR ADDITION TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We proposed to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We proposed to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We proposed to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We proposed to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We proposed to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We proposed to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
! (Outcome)	N/A	478	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.	This measure was proposed as a new measure for the 2020 performance period. We proposed to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
Comment: One commenter appreciated the addition of measures Q217: Functional Status Change for Patients with Knee Impairments, Q218: Functional Status Change for Patients with Hip Impairments, Q219: Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments, Q220: Functional Status Change for Patients with Low Back Impairments, and Q221 to the Functional Status Change for Patients with Shoulder Impairments to the Chiropractic Medicine set. The commenter pointed out, however, that many solo practitioners will struggle to make the 20 case minimums for these measures. In addition, the majority of these CQMs require the use of an extraspinal CPT code 98943 which currently is not covered by Medicare. The commenter also stated that FOTO measures have no denominator exclusions. **Response:** We thank the commenter for supporting the addition of measures Q217 through Q221 to the Chiropractic Medicine set. Measures Q217 through Q221 are MIPS CQMs, meaning that all-payer data can be utilized for determining performance. Therefore, extraspinal CPT code 98943 may be denominator eligible within all-payer data. Additionally, the measures' denominator is not limited to the single extraspinal CPT code 98943 and allows the denominator eligibility to be established by additional CPT codes covered by Medicare. Moreover, we remind the commenter that the current posted FOTO measures do contain denominator exclusions. We also refer the commenter to Tables D.25 through D.29 of this final rule as there are multiple changes being finalized for measures Q217 through Q221 regarding denominator exclusions and denominator exceptions. After consideration of the comments, we are finalizing the new *Chiropractic Medicine Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.									

B.41. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, we solicited comment on applicable measures for a Clinical Social Work specialty set, which takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that may be proposed for this new measure set in the event clinical social workers were proposed for inclusion in the definition of a MIPS eligible clinician in future rulemaking.

B.41. Clinical Social Work

MEASURES FINALIZED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

MEASURES FINALIZED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
	2872e	281	CMS149v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
*	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association /American Academy of Neurology	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association /American Academy of Neurology	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

MEASURES FINALIZED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* ! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Psychiatric Association/American Academy of Neurology	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	1365e	382	CMS177v8	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

MEASURES FINALIZED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
	2803	402	NA	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

Comment: One commenter supported all measures proposed for the Clinical Social Work set. The commenter requested the addition of several other measures for this set: Assessment of Unhealthy Alcohol Use for adolescents 12-20 every year if cessation not achieved, Assessment of Unhealthy Drug Use for adults every two years with follow up plan for cessation if not achieved, and Assessment of Unhealthy Drug Use for adolescents every two years with follow up plan for cessation if not achieved.

Another commenter supported the addition of this set and appreciated CMS revisiting the inclusion of clinical social workers (CSWs) as MIPS-eligible clinicians. CSWs are a functional member of the multidisciplinary oncology care team, and oncology CSWs (OCSWs) continue to be frequent contributors of care interventions highlighted in multiple MIPS quality metrics. The commenter suggested that measure Q047: Advance Care Plan be added to this measure set, as counseling patients in this area is not limited to oncology patients.

Response: We did not identify the three additional measures recommended for this set as MIPS quality measures and we encourage the commenter to submit them to the next Call for Measures, along with the recommendation to add Q047 to this set. We thank the commenters for supporting the new Clinical Social Work set and encourage them to submit their feedback with rationale during this solicitation process for future consideration in rulemaking. Note: Because measure Q282: Dementia: Functional Status Assessment was not finalized for removal from MIPS, it has been added to the Clinical Social Work. As a result, measures Q182: Functional Outcome Assessment was not finalized for addition to this set as it is duplicative to measure Q282 as outlined in the PFS proposed rule (84 FR 41171).

After consideration of the comments, we are finalizing the new *Clinical Social Work Measure Set* as indicated. Due to the availability of these measures as a new MIPS specialty measure set, we will take this into consideration for future rulemaking regarding whether to add clinical social workers as a MIPS eligible clinician type.

B.42. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that were proposed for this new measure set.

B.42. Audiology

MEASURES FINALIZED FOR **ADDITION** TO THE AUDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We proposed to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We proposed to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.42. Audiology

MEASURES FINALIZED FOR **ADDITION** TO THE AUDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Audiology specialty set as it is clinically relevant.
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Audiology specialty set as it is clinically relevant and the measure owner is proposing to expand the denominator to include this clinician type.
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.42. Audiology

MEASURES FINALIZED FOR **ADDITION** TO THE AUDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	N/A	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness	Audiology Quality Consortium	We proposed to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101 / N/A	318	CMS139v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Audiology specialty set as it is clinically relevant.

Comment: One commenter supported the inclusion of the new Audiology set and appreciated the multiple options for participation in MIPS that take into consideration the unique care provided by audiologists to Medicare beneficiaries. The new measures under the Audiology set would be available in addition to other MIPS measures already reported by audiologists.

Commenters requested that additional CPT codes be added to measures under this set: measure Q181: Elder Maltreatment Screen and Follow-Up Plan, measure Q182: Functional Outcome Assessment, and measure Q318: Falls: Screening for Future Fall Risk.

Response: We thank the commenters for supporting the new Audiology set and encourage them to reach out and collaborate with the measure stewards to refine the denominator eligible CPT coding.

After consideration of the comments, we are finalizing the new *Audiology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.

B.43. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that were proposed for this new measure set.

B.43. Speech Language Pathology

MEASURES FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Speech Language Pathology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Speech Language Pathology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type. The measure owner is also proposing to add coding for this clinician type for the 2020 performance period.
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Speech Language Pathology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type. The measure owner is also proposing to add coding for this clinician type for the 2020 performance period.

B.43. Speech Language Pathology

MEASURES FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed to include this measure in the Speech Language Pathology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
Comment: One commenter supported the addition of two new measures for speech language pathologists: measures Q181: Elder Maltreatment Screen and Follow-Up Plan and Q182: Functional Outcome Assessment. The addition of these measures provides SLPs the opportunity to move closer to meeting the reporting threshold. The commenter requested that additional CPT codes be added to measures Q181 and Q182. **Response:** We thank the commenter for supporting the addition of measures Q181 and Q182 to the Speech Language Pathology set and encourage them to reach out and collaborate with the measure stewards to refine the denominator eligible CPT coding. After consideration of the comments, we are finalizing the new *Speech Language Pathology Specialty Measure Set* as indicated for the 2020 MIPS performance period/2022 MIPS payment year and future years.								

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

In this final rule, we are removing 42 previously finalized quality measures from the MIPS Program for the 2022 MIPS payment year and future years. These measures are discussed in detail below. Our measure removal criteria was discussed in the CY 2019 final rule (83 FR 59763 through 59765).

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), additional criteria that we use for the removal of measures also includes extremely topped out measures, which means measures that are topped-out with an average (mean) performance rate between 98-100 percent. Beginning with the 2020 MIPS performance period/2022 MIPS payment year, we refer readers also to section III.K.3.c.(1)(d)(iv) of this final rule for additional removal criteria finalized for CY 2020.

NOTE: Since publication of the measures in Table C in CY2020 PFS proposed rule, we have determined the following measures will be retained in the 2020 MIPS performance period/2022 MIPS payment year: Q110, Q111, Q146, Q178, Q185, Q225, Q249, Q250, Q264, Q282, Q288, Q395, and Q396. As such, these measures have been removed from Table C and integrated back into the relevant previously finalized measure sets under Table B in this final rule. Our decisions not to finalize these measures for removal in this final rule are detailed in our responses to the public comments for these measures in Table Group C.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0097	046	N/A	Medicare Part B Claim Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative of previously finalized measure Q130: Documentation of Current Medications in the Medical Record that also addresses assessment of current medications at the time of a patient and eligible clinician encounter. This measure is not only duplicative but includes measure logic that has demonstrated to be historically challenging for implementation by eligible clinicians. This measure is a legacy measure from the Physician Quality Reporting Initiative that was implemented initially as a Medicare Part B claims only measure. With the expansion of collection methods being used in the program, unforeseen implementation challenges have arisen. We believe measure Q130 is the best measure to support the quality outcome of current medications being documented in the medical record. In the event that the measure is retained in the MIPS program based on stakeholder comments, we proposed to add this measure to the following specialty sets as it is clinically relevant to these clinician types: Pulmonology and Clinical Social Work.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0091	051	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry results documented.	American Thoracic Society	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program to ensure measures are not duplicative and present an opportunity to provide a meaningful impact to quality. We prefer the more robust, previously finalized measure Q52: Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy that assesses appropriate management of COPD by prescribing a long-acting inhaled bronchodilator for symptomatic patients based on spirometry test results that demonstrate FEV1/FVC < 70 percent, FEV1 < 60 percent, and patient's assessed COPD symptoms. Measure Q51 represents the process having the spirometry results reviewed and documented which is essentially a component of measure Q52. Therefore, we prefer to have eligible clinicians report the more robust measure Q52 which address spirometry results to provide the best option in pharmacological treatment. In the event that the measure is retained in the MIPS program based on stakeholder comments, we proposed to add this measure to the following specialty set as it is clinically relevant to this clinician type: Pulmonology.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	068	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy.	American Society of Hematology	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because we believe that documentation of iron stores would be considered a standard of care during administration of erythropoietin therapy. We believe this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the event that the measure is retained in the MIPS program based on stakeholder comments, we proposed to add this measure to the following specialty set as it is clinically relevant to this clinician type: Oncology/ Hematology.
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology-Head and Neck Surgery	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it represents the clinical equivalency of previously finalized measure Q93: Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use. In the circumstance an eligible clinician does not prescribe an antibiotic, most likely a topical therapy would be prescribed. However, the eligible clinician is able to prescribe both an antibiotic and topical and remain numerator compliant for this measure which does not address the overuse of systemic antimicrobial use. Therefore, we believe this measure is not providing a meaningful impact to quality improvement.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative of previously finalized measure Q182: Functional Outcome Assessment that also addresses functional assessment and possibly pain depending on which standardized tool utilized. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: add coding for physical therapists and occupational therapists to the list of denominator eligible encounters as well as add this measure to the Physical Therapy/ Occupational Therapy specialty set. The measure steward states and we agree that for individuals with osteoarthritis (OA), physical therapists and occupational therapists provide various interventions with the goals of improving muscle performance, activity and participation, and promoting physical activity. Despite these revisions offered by the measure steward, we believe that it is important to reduce duplicity within the program and prefer the more robust measure Q182 which also supports physical and occupation therapist, more frequent functional assessment, and care plan for identified functional deficiencies.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program due to the controversy surrounding the potential correlation between assessment of pain and increase in prescriptions for opioid medications. After consideration of previous stakeholder feedback, we believe this measure may have the unintended consequence of encouraging excessive prescribing of pharmacologic therapies to assist with pain management. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: expand the denominator to include coding for audiology and speech language pathology MIPS eligible clinicians and remove the denominator exception allowing for patients with severe mental and/or physical incapacities to be excluded from the numerator. The measure steward submitted this substantive change based on a literature search the supports the need for improved pain assessment and follow up in patients with dementia. In addition, we proposed to add this measure to the following specialty measure sets in the event the measure is retained in the MIPS program based on stakeholder comments as it is clinically relevant to these clinician types: Chiropractic Medicine, Clinical Social Work, Audiology and Speech Language Pathology. Despite these revisions offered by the measure steward, we believe that it is important to ensure that the MIPS quality measures support the safety of patients and have a meaningful impact on quality management of pain by all eligible clinicians.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	160	CMS52v8	eCQM Specifications	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis.	Health Resources and Services Administration	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the numerator with addition of Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis and parenteral pentamidine and oral clindamycin with primaquine to Population one. For Population two and three, we would add intravenous pentamidine to the "Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis" value set. In alignment with these updates, the measure steward has is updating and creating definitions related to CD4 Count Tests to include oral clindamycin and primaquine for population 1 and update logic in all three numerators to allow for 'Medication Active' documentation in addition to 'Medication, Order' documentation for appropriate capture of either an active or ordered medication. Additionally, we would adopt the measure steward's substantive change to remove Leucovoin as a medication option and add oral Clindamycin to align with guideline updates. Additionally, we would update logic for denominator exceptions in population 1 to reflect "3 months or less after". Additionally, if the measure is not finalized for removal from the MIPS program, we proposed to remove the measure from the Allergy/ Immunology specialty set since this measure is not applicable to this specialty as Allergy/Immunology specialists do not diagnose, treat or manage HIV/AIDS patients. In addition, if the measure is retained in the MIPS program based on stakeholder comments we proposed to add this measure to the following specialty set as it is clinically relevant to this clinician type: Pulmonology. Despite these revisions, we believe this measure is not providing a meaningful impact to quality improvement due to lack of adoption by eligible clinicians.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0130	165	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.5 percent for the MIPS CQMs specifications collection type For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
0131	166	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in (83 FR 59761 through 59763). The average performance for this inverse measure is 1.3 percent for the MIPS CQMs specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because previously finalized measure Q177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity assesses the same patient population, but requires more frequent assessment in order to be numerator compliant making it a more robust measure.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0564 / 0564e	192	CMS132 v8	eCQM Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The measure steward proposed to update the language to better clarify how the measure is currently implemented. They also requested to update the denominator exclusion data elements/value sets; removing 'Aphakia and Other Disorders of Lens,' 'Cysts of Iris, Ciliary Body and Anterior Chamber,' 'Enophthalmos,' and 'Prior Pars Plana Vitrectomy' and adding 'Glaucoma Associated with Congenital Anomalies, Dystrophies and Systemic Syndromes,' 'Other Endophthalmitis,' and 'Purulent Endophthalmitis'. We do not believe these changes will have an impact on performance rates because the measure is extremely topped out. In addition, the measure steward is updating the measure to specify the complication should be assessed of the operative eye. This is an inverse measure with extremely high performance rate of 0.9 percent for eCQM specifications collection type and 0.2 percent for MIPS CQMs collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the eCQM and MIPS CQMs specifications collection types are considered extremely topped out. Average performance rates are based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

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0428	223	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with General Orthopedic Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program as the measure steward, Focus on Therapeutic Outcomes, Inc. (FOTO) no longer supports the inclusion of the measure. The patient population within this measure is captured in the FOTO measure A.4: Functional Status Change for Patients with Neck Impairments. In the event we do not finalize A.4: Functional Status Change for Patients with Neck Impairments, we would maintain this measure with the following substantive changes: update the numerator to require meeting or exceeding the risk adjusted prediction of the functional status change to be a Performance Met, move the current denominator exclusions to denominator exceptions, add denominator exclusion for patients with diagnosis of a degenerative neurological condition at any time before or during the episode of care, and add denominator exceptions for ongoing care not indicated: patient self-discharged early, patient discharged after only 1-2 visits due medical events, patient seen only 1-2 visits. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
N/A	255	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).	American College of Emergency Physicians	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure narrows the eligible patient population to the Rh-Negative pregnant women which has not been able to create a benchmark. This is a result of the limited patient population and measure adoption which does not provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. This does not align with the meaningful measure initiative. We encourage measure stewards to develop a measure that expands the patient population to those that had their Rh Status evaluated in the Emergency Department (ED) and received Rh-immunoglobulin (Rhogam) if Rh-negative.

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N/A	262	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Image Confirmation of Successful Excision of Image-Localized Breast Lesion:** Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion, focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy.	American Society of Breast Surgeons	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 100 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

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N/A	271	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients regardless of age with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. Individuals who received an assessment for bone loss during the year prior and current year are considered adequately screened to prevent overuse of X-ray assessment.	American Gastro-enterological Association	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the substantive changes submitted by the measure steward would require a less meaningful quality action and extend the prednisone usage from 60 to 90 or greater consecutive days. The revised measure's quality action would be simplified to prescribing supplements such as calcium and/or vitamin D optimization. Additionally, the measure steward proposed to replace the term "Loss Assessment" with "Health Optimization" throughout the measure, define the patient population as 18 and over, as well as updating the numerator definition to "Documentation that calcium and/or Vitamin D optimization has been ordered or performed. This includes, but is not limited to, checking serum levels, documenting use of supplements or prescribing supplements" to better align with the measure's intent. The current measure requires a Central Dual-energy X-Ray Absorptiometry (DXA) and documented review of systems and medication history or pharmacologic therapy (other than minerals/vitamins) for osteoporosis prescribed within the past two years. We agree that patients without risk factors would not be appropriate for frequent DXA scans as the current quality measure requires. The measure steward's substantive changes for the measure do not account for patients with high risk factors, which may warrant additional screening and pharmacologic treatment. The measure would be more robust if it was revised to assess based on multiple clinical criteria such as age, risk factors, etc. We encourage the measure steward to submit a new measure that takes into account risk factors and require the appropriate clinical action.

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N/A	325	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition.	American Psychiatric Association	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program as we have reexamined public comments received during last year's rulemaking cycle. Stakeholders commented that it is burdensome for clinicians to retrieve specialists' reports for all patient visits. This insinuates the communication may be happening, but the co-morbid treating physician is not looking for and/or considering the MDD status. Additionally, this measure is duplicative to previously finalized measure Q374: Closing the Referral Loop: Receipt of Specialist Report which specifies numerator compliance as receipt of report from the referring eligible clinician. In the event that the measure is maintained, we proposed to add this measure to the following specialty sets: Clinical Social Work.
1667	328	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited patient population and adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. There were zero submissions for the 2017 performance period.
N/A	329	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is a catheter at the time maintenance hemodialysis is initiated.	Renal Physicians Association	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the event that the measure is retained in the MIPS program based on stakeholder comments, we proposed to add this measure to the following specialty set based on stakeholder feedback: Nephrology.

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N/A	330	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter.	Renal Physicians Association	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians.
N/A	343	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate:** The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.	American Society for Gastrointestinal Endoscopy	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program after review of previous stakeholder feedback, scoring implications, and attribution to the MIPS eligible clinician. The measure does not account for variables which may influence the adenoma detection rate such as geographic location, socioeconomic status of patient population, community compliance of screening, etc. Due to the measure construct, benchmarks calculated from this measure are misrepresented and do not align with the MIPS scoring methodology where 100 percent indicates better clinical care or control. Guidelines and supplemental literature support a performance target for adenoma detection rate of 25 percent for a mixed gender population (20 percent in women and 30 percent in men). In addition, the measure does not account for MIPS eligible clinicians that fail to detect adenomas, but may score higher based on the patient population.
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	We proposed the removal of this measure (finalized in (81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients without Major Complications (Discharged to Home by Post-Operative Day #2). Measure Q344 is a more comprehensive measure accounting for the patient population found within measure Q345 as well as assessing for complications and appropriate length of stay. Based on input from the measure steward, we proposed the substantive change of replacing the "or" with "and" in the title and the numerator statement in the circumstance that this measure is not finalized for removal. Despite these revisions, this measure is still duplicative in nature and less comprehensive as compared to measure Q344.

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1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q260: Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2). Measure Q260 is a more comprehensive measure accounting for the patient population found within measure Q346 as well as assessing for complications and appropriate length of stay. Based on input from the measure steward, we proposed the substantive change of replacing the "or" with "and" in the title and the numerator statement in the circumstance that this measure is not finalized for removal. Despite these revisions, this measure is still duplicative in nature and less comprehensive as compared to measure Q260.
1534	347	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Are Discharged Alive:** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q259: Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2). Measure Q259 is a more comprehensive measure accounting for the patient population found within measure Q347 as well as assessing for complications and appropriate length of stay.
N/A	352	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.	American Association of Hip and Knee Surgeons	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.8 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

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NA	353	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.	American Association of Hip and Knee Surgeons	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.6 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
N/A	361	N/A	MIPS CQMs Specifications	Structure	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are submitted to a radiation dose index registry that is capable of collecting at a minimum selected data elements.	American College of Radiology	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this is not furthering quality care, but simply submitting to a radiation dose index and does not deter excessive radiation. Despite this structure measure supporting patient care, it does not measure quality care that directly impacts patients. We believe this measure is not providing a meaningful impact to quality improvement to require radiation reduction.
N/A	362	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12 month period after the study.	American College of Radiology	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this is not furthering quality care, but simply setting up a database. Despite this structure supporting patient care, it does not measure quality care that directly impacts patients. We believe this measure is not providing a meaningful impact to quality improvement.

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0712e	371	CMS160 v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure only captures the process of depression screening and is duplicative of previously finalized measure Q370: Depression Remission at Twelve Months. Measure Q370 is a more robust outcome measure, requiring depression remission for numerator compliance. The screening element found within this process measure is a part of logic for measure Q370. In the event that the measure is retained in the MIPS program based on stakeholder comments, we proposed to add this measure to the following specialty set as it is clinically relevant to the clinician type: Pediatrics.
N/A	372	CMS82v7	eCQM Specifications	Process	Community/Population Health	**Maternal Depression Screening:** The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life.	National Committee for Quality Assurance	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because denominator eligibility is determined by the visits to the child's MIPS eligible clinician. The quality action would not be attributed to the child's MIPS eligible clinician, but rather to the obstetrician or primary care provider of the mother. The measure does not account for instances where the mother is not present for the child's visits.
N/A	388	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy):** Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.	American Academy of Ophthalmology	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.4 percent for the MIPS CQMs specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

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N/A	403	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end -stage renal disease (ESRD) who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care.	Renal Physicians Association	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. This concept would be more inclusive and better represented if the denominator was expanded to include patients with multiple chronic conditions.
N/A	407	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. Nafcillin, Oxacillin or Cefazolin) as definitive therapy.	Infectious Diseases Society of America	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.7 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: add criteria for denominator eligibility to include Diagnosis for Bacteremia (ICD-10-CM): R78.81 AND Methicillin susceptible Staphylococcus aureus infection as the cause of diseases classified elsewhere (ICD-10-CM): B95.61. Despite these revisions offered by the measures steward, we do not believe this will affect the average performance for this measure.

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0711	411	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Six Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission six months (+/- 60 days) after an index event date.	Minnesota Community Measurement	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this patient population and quality action are duplicative of previously finalized measure Q370: Depression Remission at Twelve Months but vary in timeframe in which depression remission is required. The extended timeframe allows assessment of patient to ensure management and prevention of depression relapse. American Psychiatric Association (2010) states "Continuation therapy is the four-to-nine month period beyond the acute treatment phase during which the patient is treated with antidepressants, psychotherapy, ECT or other somatic therapies to prevent relapse. Relapse is common within the first 6 months following remission from an acute depressive episode; as many as 20-85 percent of patients may relapse." In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the denominator allowing PHQ-9/PHQ9M to be administered during the index encounter or up to 7 days prior to encounter. In addition, we proposed to add this measure to the following specialty measure sets in the event the measure is retained in the MIPS program based on stakeholder comments within the program as it is clinically relevant to these clinician types: Pediatrics and Clinical Social Work. Despite these revisions offered by the measures steward, we prefer measure Q370 which supports the quality outcome depression remission at 12 months.
1523	417	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive:** Percentage of patients undergoing open repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	We proposed the removal of this measure (finalized in (81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q258: Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7). Measure Q258 is a more comprehensive measure accounting for the patient population found within measure Q417 as well as assessing for complications and appropriate length of stay.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per American College of Obstetrics and Gynecology (ACOG), American Urogynecologic Society, and American Urological Association guidelines.	American Urogynecologic Society	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the patient population is captured within previously finalized measure Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%). While the quality action requires persistent beta-blocker treatment, the performance period is narrowed to only include the patients hospitalized and discharged for the first 6 months of the performance period. This does not include patient hospitalized and discharged after July 1, thus missing a substantial portion of the patient population. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the denominator exclusion adding advance illness and frailty. Despite these revisions offered by the measure steward, we maintain that measure Q007 will capture the patient population sampled within this measure and allows for a 12 month performance period.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0733	446	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Operative Mortality Stratified by the Five STS-EACTS Mortality Categories:** Percent of patients undergoing index pediatric and/or congenital heart surgery who die, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, even if after 30 days (including patients transferred to other acute care facilities), and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, stratified by the five STAT Mortality Levels, a multi-institutional validated complexity stratification tool.	Society of Thoracic Surgeons	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the denominator has a very limited patient population. We believe this measure does not align with the meaningful measure initiative. The limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the event that the measure is retained in the MIPS program based on stakeholder comments, we proposed to add this measure to the following specialty set as it is clinically relevant to this clinician type: Thoracic Surgery.
1857	449	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Percentage of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies.	American Society of Clinical Oncology	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because clinically we believe this to be standard of care. The performance data does not support a meaningful gap. The average performance for this measure is 97.4 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the denominator definition to align with current guidelines as referenced in Table D. 68: Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy of this document.
N/A	454	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer with more than one emergency department visit in the last 30 days of life.	American Society of Clinical Oncology	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this may be outside of the eligible clinician's control. We believe previously finalized measure Q455: Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better) is a related concept that can be a better indicator of compassionate outcomes to the end of life care for oncology patients.

TABLE C: Previously Finalized Quality Measures Finalized for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0215	456	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died From Cancer Not Admitted to Hospice (lower score – better):** Percentage of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the concept would be captured in measure Q457: Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better) and is the more robust measure as it requires at least 3 days of hospice prior to death.
N/A	467	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Developmental Screening in the First Three Years of Life:** The percentage of children screened for risk of developmental, behavioral and social delays using a standardized screening tool in the 12 months preceding or on their first, second, or third birthday. This is a composite measure of screening in the first three years of life that includes three, age-specific indicators assessing whether children are screened in the 12 months preceding or on their first, second or third birthday.	Oregon Health & Science University	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program after review of denominator of this process measure is not able to specifically target a pediatric patients primary clinician for performance of developmental screening. The measure owner submitted a substantive change to revise the denominator eligible coding to include well-child visits. The well-child visit encounters would likely include the attestation of the numerator's quality action and therefore inflate performance of the measure. While we agree that screening pediatric patients for development milestones is indicative of quality interactions with patients, we believe that the complexity of implementing the change creates a less meaningful assessment of MIPS eligible clinicians.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	PPRNet	We propose the removal of this measure (finalized in 83 FR 60108) as a quality measure from the MIPS program because it is duplicative of measure A.3: Adult Immunization Status proposed in this proposed rule. This new measure, if finalized, is a more robust immunization measure which requires multiple age appropriate preventive immunizations. We are proposing to remove this measure to be consistent with ensuring measures are not duplicative and present an opportunity to provide a meaningful impact to quality.

TABLE C: Summary of Comments and Responses

Comment: One commenter opposed the removal of measure Q046: Medication Reconciliation Post Discharge, stating that the proposed replacement of this measure with measure Q130: Documentation of Current Medications in the Medical Record is not appropriate for patients who are at high risk post discharge.

One commenter opposed the removal of measure Q046 as it is in the current CQMC core set for ACO/Primary Care. At the most recent meeting of the CQMC, the CQMC preferred measure Q046 over measure Q130, stating that both measures are check box and may not show evidence of improved patient outcome. Another commenter requested that measure Q046 not be removed from the MIPS program until the CQMC has completed its maintenance cycle review of this measure expected by the end of 2019.

Several commenters opposed the removal of Q046, stating that measure Q130 does not reference use of the measure by a clinical pharmacist. Removing the measure may preclude pharmacists due to the measure Q130's use of the term "eligible clinician." The commenters urged CMS to explore a new measure that focuses on ensuring that the best reconciled medication list is available in all of the patient's health care locations, including post-discharge.

One commenter preferred NQF #2988's approach to measure attribution, date of reconciliation, medication assessment process, and inclusion of allergy and adverse drug event documentation requirements.

Response: We appreciate the commenters' feedback. CMS believes that measures Q046 and Q130 are duplicative in measurement as both measures review current medications, which may represent the reconciliation of medication post discharge, and would represent the same patient population. Due to the overlap, measure Q130

TABLE C: Summary of Comments and Responses

represents a broader population of patients since it is not just focused on patients that have a 30-day inpatient discharge. We agree that it is advantageous for patients to have their medications reviewed post discharge, although we believe the quality action represented in measure Q130 would support the same quality action. In reference to the concern about the preclusion of pharmacists and team-based approach, the quality action of measures Q046 or Q130 does not require the consultation of a pharmacist, although may be appropriate in some instances. We strive to maintain robust measures that meet the meaningful measures initiative and we encourage the commenter to work with measures' developers to submit new, more robust measures through the Call for Measures process that evaluates documentation of medication in the medical record. We attempt to align with CQMC, but believe this measure is duplicative of a more broadly applicable measure. As MIPS moves forward, we will continue to explore ways to align measurement across programs. We reviewed NQF #2988: Medication Reconciliation for Patients Receiving Care at Dialysis Facilities and believe this measure would not be an adequate replacement for measure Q130. This measure is focused on all patients receiving dialysis services whereas measure Q130 is broadly applicable to all patient types in a variety of clinical settings. We believe that this population of patients would be captured within office visits currently found within the denominator of measure Q130. We will take this into consideration for future substantive change proposals to include this additional care setting of dialysis services. Alternatively, we encourage the commenter to submit NQF #2988 or other measures they believe may represent beneficial quality measures within to the Call for Measures once fully tested at the clinician level.

Comment: One commenter supported the removal of measure Q051: Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation, citing CMS' rationale that the measure is duplicative of measure Q052, Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy. Although the commenter preferred both quality measures be retained, the commenter supported CMS' proposal to use measure Q052 to support the use of spirometry to diagnose COPD. Another commenter agreed with the removal of measure Q051 because if a patient has COPD but is asymptomatic at the time, the patient would not be captured in the denominator due to the wording of the specification. The commenter asked if there should there be a similar measure that captures patients who are well maintained and asymptomatic, and if EHRs able to this capture this data.

Response: We thank the commenters for supporting the removal of measure Q051 and agreeing that measure Q052 is a more robust measure. We thank the commenter for their concern with certain patient populations not being captured within measure Q052, however, measure Q051 does not require continual spirometry evaluation, but rather documentation of a single spirometry result. Most likely, this would be captured at the time of diagnosis as discussed in the clinical recommendation statement within measure Q051, and the above patient population of concern is not required to have continual evaluation for this measure. We encourage the other commenter to collaborate with the measure steward to revise current MIPS measures for proposed implementation in future years or to develop new robust, meaningful measures to submit to the Call for Measures once fully tested at the clinician level.

Comment: One commenter opposed the removal of measure Q091: Acute Otitis Externa (AOE): Topical Therapy as it is an important measure for otolaryngology, is evidence-based, and is applicable to the practice of many otolaryngologists and other specialties who treat these patients.

Response: We thank the commenter for their comment. We agree that measure Q091 is evidence-based, but it does not address the inappropriate use of antibiotics. In the circumstance an eligible clinician does not prescribe and antibiotic, most likely a topical therapy would be prescribed. However, the eligible clinician is able to prescribe both an antibiotic and topical and remain numerator compliant for this measure. Despite their limited utility, about 20-40 percent of patients with AOE receive oral antibiotics, often in addition to topical therapy (Rosenfeld, et al., 2014).

Comment: Several commenters opposed the removal of rheumatology measures Q109: Osteoarthritis (OA): Function and Pain Assessment and Q178: Rheumatoid Arthritis (RA): Functional Status Assessment. These measures are clinically relevant for rheumatology and the removal of these rheumatology-specific measures dramatically reduces the number of quality measures that are applicable to this specialty. Removing these measures will add unnecessary burden to the commenter's practice and negatively impact its scoring and payment incentive. The rationale for removal of measures Q109 and Q178 is that they are duplicative to measure Q182: Functional Outcome Assessment. The commenter stated that both of these measures should be kept, as they are clinically relevant and important for these rheumatoid arthritis and osteoarthritis as two diseases that affect a large patient population at their practice.

Another commenter opposed the removal of these measures, stating that measure Q182 is a measure used by physical therapists. Another commenter opposed the removal of measure Q109 and preferred this existing measure over measure Q182 because it is more targeted to a population that will benefit from functional assessment.

Response: We thank the commenters for their comments. We believe that duplicative measures are counterintuitive to the meaningful measures initiative that promotes more focused quality measure development towards outcomes that are meaningful to patients, families and their providers. Measures Q109 is a measure that has a focus on functional outcomes for patient populations that are disease specific. Measure Q182 is a disease non-specific, broadly applicable measure and allows eligible clinicians to use an assessment that is validated and meets their individual patient's clinical needs. The measure supports tools that address functional as well as pain aspects for these clinical assessments. The clinical rationale of the measure indicates "The tool should be selected based on purpose of the assessment and type of injury sustained (Lesher, et al, 2017; and Wales, et al., 2016). Utilization of validated pain and function scales help to differentiate treatment approaches in order to improve the patient's ability to function (ICSI, 2012).

We value stakeholder feedback and agree that measure Q178 is clinically relevant for rheumatology and we believe the proposed measure changes ensure that clinicians are utilizing the preferred assessment tools for standardization of performance. According to the American College of Rheumatology's RA treatment guidelines, functional status assessment using a standardized, validated measure should be performed routinely for RA patients, at least once per year, but more frequently if disease is active. As a result, we are not finalizing the removal of measure Q178 from MIPS and will finalize the substantive change for this measure outlined in the 2020 PFS proposed rule (84 FR 41164) shown under Table D.83 of this final rule.

Comment. One commenter urged CMS to defer removal of measures Q110 and Q111 for an additional year until the new Adult Immunization Status measure is proven and determined to be reportable by surgeons and because removal of measure Q110 would impact the surgeon's workflow. Another commenter opposed removal of measure Q110 because there are an estimated 1,100 dialysis patients that die each year of influenza, and most of these deaths can be prevented by influenza immunization. Several commenters stated that CMS should not remove EHR reportable eCQM measures Q110 and Q111 when alternative eCQM measures are not available to be reported.

One commenter agreed with the removal of measures Q110 and Q111.

TABLE C: Summary of Comments and Responses

Response: We thank the commenters for their comments. Per our discussion on the Adult Immunization Status measure under Table A.3, we are retaining measures Q110 and Q111 because the new measure Adult Immunization Status measure is not being finalized for the 2020 MIPS performance period/2022 MIPS payment year due to the imminent changes in clinical guidelines for pneumococcal vaccination and because we believe it is advantageous to evaluate the clinical guidelines and Adult Immunization Status measure for inclusion through future rulemaking. We would encourage the commenter to work with the measure steward to revise the measure to better fit the surgeon's workflow for possible implementation in future years. We agree that the administration of the influenza vaccine is critical for certain patient populations and would note that the Adult Immunization Status measure has an influenza vaccine component. We are finalizing substantive changes for measures Q110 and Q111 as outlined in the 2020 PFS proposed rule (84 FR 41158 and 41159) shown under Tables D.81 and D.82 of this final rule.

Comment: Several commenters opposed the removal of measure Q131: Pain Assessment because physical and occupational therapists cannot prescribe opioids. Therefore, while it might make sense to eliminate this measure for physicians, it makes no sense to eliminate this measure for physical and occupational therapists. Another commenter did not support the removal of Q131, stating that there is no requirement within this measure that opioids must be used to improve a patient's pain level. Another commenter opposed the removal of measure Q131 because it targets two of CMS' highest priority areas— measures based on outcomes and measures targeting opioid use, management, and treatment.

Two additional commenters opposed the removal of measure Q131 as chiropractors are only being reimbursed for manipulation codes for two claims-based quality measures: Q131 and Q182: Functional Outcome Assessment. These current limitations have diminished the number of chiropractors willing to opt-in to MIPS. Chiropractors are not allowed to prescribe opioid medications and chiropractic care is an excellent tool in the fight against opioid abuse.

Another commenter opposed the removal of measure Q131 given that approximately 100 million Americans live with chronic pain. The measure focuses on appropriate follow-up, which is not limited to medication use. A separate measure maintained by the American Academy of Neurology and the American Psychiatric Association specifically addressing pain for patients with dementia could be retired given this measure's proposed expansion to include those who are non-verbal. Another commenter opposed the removal of Q131 as it would negatively impact rheumatology practices and reduce the number of high priority measures available to them. Another commenter stated that speech language pathologists are not authorized under any state law to prescribe medications; therefore, there is no increased risk when they complete the pain assessment.

Response: We thank the commenters for their feedback and concerns cited on removing measure Q131. However, measure Q131 is not limited to clinicians (that is, speech language pathologists) unable to prescribe medications, but is available for a broad range of eligible clinician types. As measure Q131 is unable to be revised at this time, retaining it within MIPS would still allow the measure to be utilized by clinicians who are able to prescribe opioids. We believe that it is important to consider the negative impact our measures may inadvertently have on current health crises, such as the opioid epidemic, and support efforts that ensure positive outcomes in patient care and deter the possibility of overtreatment of pain. We encourage the submission of measures that are structured in a way that manages pain, yet deters opioid use. Regarding the comment addressing the changes to an American Academy of Neurology and American Psychiatric Association maintained measure, we currently do not have a measure that addresses pain in patients with dementia that is being expanded to include non-verbal patients and encourage the commenter to collaborate with the measure stewards to refine the measure for implementation in future years. In an abundance of caution, as the risks outweigh the quality of care assessed from this measure, we are finalizing the removal of measure Q131.

Comment: One commenter opposed the removal of four radiology measures from MIPS: measures Q146, Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms, Q225, Radiology: Reminder System for Screening Mammograms, Q361, Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry, and Q362, Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes. Ninety-five percent of radiology measures are topped out and four are proposed for removal in 2020, with two other measures removed in 2019. The commenter also stated that many high-performing measures are still showing a low adoption rate among radiologists, thus a reason for the high performance score may be a result of a small pool of high-performing individuals choosing to report certain measures. This would skew the average score and mask the actual performance gap than if the measure was reported across a larger number of practices, including those with worse performance on the measures in question.

The rationale for removing measures Q361 and Q362 is that the measures are process/structural or not directly related to patient outcome. The commenter stated that is especially problematic for radiology in that the imaging services are typically provided at an early state of the care process, and process measures support care improvement across the care continuum. Additionally, both of those measures were part of the Optimizing Patient Exposure to Ionizing Radiation Physician Quality Reporting System (PQRS) specialty measures group until MIPS began in 2017. The performance data on which these have been assessed is largely based on the limited number of cases (20) to be reported when using a measures group. This skews the actual performance gap toward higher scores from higher performing groups.

The other two measures, Q146 and Q225, proposed for removal are specific to radiologists performing screening mammography. Removal of the two breast imaging measures would leave many groups/eligible clinicians who only have a case mix relative to these mammography measures (typical in community and rural settings) without any practice-relevant measures to report. Additionally, breast cancer screening may be ideal as an initial concept for a radiology MVP.

Response: We thank the commenters for their feedback on measures Q146, Q225, Q361, and Q362. After consideration of the feedback, we are retaining measures Q146 and Q225 to ensure that MIPS eligible clinicians/groups who only have a case mix relative to screening mammography would have applicable measures within the Diagnostic Radiology set. Although we acknowledge that a small sample size of high performing clinicians may lead to an overall high performance rate, CMS believes that retaining the measures Q361 and Q361 in MIPS will not lead to increased adoption given the fact that the measures have been available for multiple years. Therefore, we conclude that eligible clinicians do not believe this measure supports quality outcomes or is meaningful for their scope of practice. CMS encourages the commenter to collaborate with measure stewards to develop an outcome-based measure that assesses the safe practices of radiation exposure by setting an appropriate threshold to determine performance.

We acknowledge that these measures support processes related to outcomes, and we are motivated to implement outcome based measures that support direct patient care. While we recognize that measure stewards may have difficulties in developing outcome based measures, we believe it is important to include measures that support the meaningful measure initiative. The lack of a quality measures does not preclude the creation of clinical processes that drive positive outcomes for patients. Therefore, we are finalizing removal of measures Q361, and Q362 for the 2020 MIPS performance period/2022 MIPS payment year and future years.

Comment: One commenter supported the removal of measure Q160: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis from the eCQM measure type.

TABLE C: Summary of Comments and Responses

Response: We thank the commenter for supporting the removal of measure Q160.

Comment: One commenter disagreed with the removal of measure Q165: Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate and measure Q166: Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG) from the Thoracic Surgery set. The commenter indicated that a high performance rate on a specific measure does not necessarily mean that a measure is not meaningful. Removing these measures may create serious unintended consequences including negative effects on patient care, and could also make it difficult to track performance on these measures over time.

Response: We thank the commenter for their consideration and encourage them to collaborate with measure stewards to develop a quality measure that assess a more comprehensive list of complications for CABG surgery, including, but not limited to, infection, mortality, and re-exploration. A comprehensive composite measure would likely identify a performance gap that allows eligible clinicians to maximize their potential quality performance category score. Additionally, by removing these extremely topped out measures, we are attempting to reduce reporting burden where there is little room for improvement.

Comment: One commenter opposed the removal of measure Q178: Rheumatoid Arthritis (RA): Functional Status Assessment by replacing it with the non-rheumatology-specific measure Q182: Functional Outcome Assessment, as this would remove a specialty-specific measure from the MIPS program. Measure Q178 could also be used in a rheumatology-specific MVP. The commenter indicated that measure Q178 is an important steppingstone for the commenter's work toward developing and implementing rheumatology outcome measures and its work with the NQF to develop a patient-reported functional status outcome measure. Replacing measure Q178 with measure Q182, in effect, removes restrictions around requiring specific tools to meet the measure, thereby lowering performance thresholds for rheumatology providers. Additionally, measure Q182 is more focused on functional status assessments and care plans within physical and occupational therapy.

Another commenter disagreed with CMS' rationale for removing measures Q178 and Q179: Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis, including that other measures are more appropriate and that the rheumatoid arthritis measures are duplicative. If practices begin reporting on other functional assessment measures, the feedback will not be directly relevant to rheumatology practices and patients as the data will include that of other specialties and for other diseases. If CMS is unwilling to retain these measures, the Agency should at least parse out data based on the specialty reporting the measure and associated diagnoses.

Another commenter opposed removal of five measures from MIPS that would be removed from the Rheumatology set given the impact of rheumatoid arthritis has on the Medicare population. The more specialty measures are removed, the less relevant CMS' quality programs are to specialists.

Response: We thank the commenters for their comments opposing the removal of measures Q178 and Q179. Measures Q179 and Q177: Rheumatoid Arthritis (RA) Periodic Assessment of Disease Activity assess the same patient population for disease activity, however, measure Q177 requires this assessment to be completed during at least 50 percent of the eligible encounters for each patient as opposed to only once per performance period, ensuring the assessment is being given on a more consistent basis. Measure Q182 only includes settings without any diagnosis coding within the denominator criteria as this is a broadly applicable measure, relevant to MIPS clinician types beyond physical and occupational therapy.

We value stakeholder feedback and agree that measure Q178 is clinically relevant for rheumatology and we believe the proposed measure changes ensure that clinicians are utilizing the preferred assessment tools for standardization of performance. According to the American College of Rheumatology's RA treatment guidelines, functional status assessment using a standardized, validated measure should be performed routinely for RA patients, at least once per year, but more frequently if disease is active. As a result, we are not finalizing the removal of measure Q178 from MIPS and will finalize the substantive changes for this measure outlined in the 2020 PFS proposed rule (84 FR 41164) shown under Table D.83 of this final rule. We encourage collaboration with the measure steward to refine the measure for MIPS for future program years. We agree that this measure may be applicable to a Rheumatology-specific MVP and encourage the commenter to look for future rulemaking and solicitation for recommendations regarding MVPs.

Comment: One commenter agreed that measure Q179: Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis should be removed from MIPS as it anticipates it will soon be a topped-out measure.

Response: We thank the commenter for supporting the removal of measure Q179.

Comment: One multi-society commenter requested that measure Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use remain in MIPS until meaningful alternatives can be developed. The commenter stated that for colonoscopy to be cost-effective, the intervals between examinations must be optimal. The commenter disagreed with benchmarks established by CMS suggesting this measure is topping out, because that does align with the evidence from surveys of practice. The commenter also requested that measure Q185 remain in the MIPS program so that it may be included in MVP for colorectal cancer screening through which it believes more accurate benchmarks for the measure will be developed. The commenter responded that the measure is being proposed for removal from MIPS because the measure was not updated by the measure steward to align with new guidelines and stated that measure Q185 should remain in MIPS until updated guidelines are released and the impact on this measure can be evaluated.

One commenter supported removal of measure Q185. While the measure is currently included in the CQMC Gastroenterology Core Set, the commenter supported removing the measure from this program until the measure steward has updated the specifications to align with recently updated clinical guidelines.
Response: We appreciate the concern cited for measure Q185. We originally proposed this measure to be removed for the 2019 performance period to allow the measure to be updated with new guidelines. After further discussion with the measure steward, they now support continued inclusion of measure Q185 in MIPS, given it is a well-established, valid measure with variability still seen in practice. It is anticipated that new guidelines will be released that may necessitate a future substantive change of the measure.

Comment: One commenter opposed the substantive change to measure Q191: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery (eCQM: CMS133v8). Within the context of this comment, the commenter opposed the removal of measure Q192: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (eCQM: CMS132v8), including to the changes to 2020 eCQM specifications for measures Q191 and Q192 (see response under Table C for further details on measure Q192). The commenter stated that the proposed change should not be finalized for the registry versions of the measures and should be reversed for the eCQM versions of measures Q191 and Q192, which have already been published. Another commenter opposed the removal of measure Q192 and Q388: Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy) as these are two important patient safety measures. The commenter encouraged CMS to retain measures Q192 and Q388 and consider the application of the flat percentages scoring methodology for these measures.

TABLE C: Summary of Comments and Responses

One multi-organization commenter also opposed the elimination of two cataract surgery outcome measures Q192 and Q388 due to topped out status without accounting for the clinical relevance of these measures. Maintenance of these measures, either through the EHR or registry, allow cataract surgeons real-time awareness of complication rates and provide real opportunities for quality improvement where necessary. The commenter urged CMS to conduct more thorough analyses of factors potentially influencing topped out performance. Another commenter cited concerns with CMS' proposal to eliminate measure Q192 because cataract surgeons frequently state it is the most meaningful measure they report on because it is a true indicator to patients whether the physician provides good quality care.

One commenter supported the removal of measure Q192: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures from the eCQM measure type.

Response: We thank the commenter for supporting the removal of measure Q192. As the performance on measures Q192 and Q388 is extremely high and unvarying they do not allow meaningful benchmarks to be established. By removing measures that are extremely topped out, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as these measures' topped out status would limit the score awarded per the 2019 Benchmark File.

Comment: One commenter opposed the removal of four extremely topped out pathology measures from the MIPS program that would impact the number of measures available to report for pathologists: measures Q249: Barrett's Esophagus, Q250: Radical Prostatectomy Pathology Reporting, Q395: Lung Cancer Reporting (Biopsy/Cytology Specimens), and Q396: Lung Cancer Reporting (Resection Specimens). Removal would limit the pathology specialty set to two measures, both of which are skin cancer measures and thus would not be applicable to more than 50 percent of pathologists.

The commenter opposed the removal of the four measures based on its scoring analysis. Extrapolating from the commenter's QCDR, half of the practices who reported as a group did not meet the 20 case minimum for measure Q397 and 92 percent of individuals who reported did not meet the 20 case minimum. Therefore, most pathology practices who are single specialty would not be able to report the two measures left in the Pathology set and have no measures available to report, thus ending up with a negative MIPS payment adjustment. The commenter also requested that CMS apply the Eligible Measure Applicability (EMA) process automatically to practices who are unable to report on a minimum of six measures. In summary, the commenter requested that CMS maintain the current pathology specialty measure set and add the proposed measure Q440, even if CMS finalizes its proposal to increase data completeness to 70 percent.

A second commenter also opposed the removal of the four pathology measures, stating that only about 50 percent of practicing pathologists will be able to be scored on quality. Given that most pathologists are exempted from promoting interoperability and unable to be scored on cost, the rest will receive a neutral payment adjustment since they can only be scored in the improvement activities category.

Response: In the CY 2020 PFS proposed rule (84 FR 40749), we indicated that changes were not made to the Pathology set. In this final rule, we clarified that we in fact did propose changes to the Pathology set, as described in the CY 2020 PFS Proposed Rule (84 FR 41020 through 41022). We thank the commenters for their concerns on the proposed removal of the pathology measures and agree that many eligible clinicians would not meet the case minimum and would therefore be unable to utilize measures Q397 and Q440 leaving them with no applicable quality measures for submission. As a result, we are not finalizing the removal of measures Q249, Q250, Q395, and Q396 for the 2020 MIPS performance period/2022 MIPS payment year and are adding measure Q440 as requested.

Comment: One commenter opposed the proposed removal of measure Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer that measures the percentage of clinically node negative breast cancer patients before or after neoadjuvant systemic therapy, who undergo sentinel lymph node (SLN) procedure. The commenter opposed the removal of measures based solely on extremely topped out or topped out status. Assessing value of care for a patient differs from placement of a measure into a payment program. The commenter stated that when CMS removes a valued measure such as Q265 because it is "topped out" the Agency is sending the wrong message to the field. The commenter would rather build on topped out measures so that patients are subjected to all the proper aspects of a care model in support of quality.

Response: We thank the commenter for their comment and upon further consideration have decided to retain measure Q264. This decision was made in order to have a breast specific measure within the General Surgery set for clinicians with this focus. Measure Q264 also shows some variation within the performance data submitted across MIPS eligible clinicians potentially allowing for movement within the performance rate. However, when reviewing the performance data for Q265, there was little to no variance and remained extremely topped out. We believe this measure represents a valuable measure concept and the removal of measure Q265 should not preclude clinicians from completing the quality action, however measures with topped out performance do not allow for the creation on meaningful benchmarks to discern quality among eligible clinicians. We do agree with the commenter that this measure could be built upon to create a measure with a broader focus of a care model. We would encourage the commenter to collaborate with measures stewards to develop a measure and submit to the Call for Measures when tested at the clinician level.

Comment: One commenter recommended that CMS delay removing measure Q271: Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment from the MIPS program until the CQMC has completed its maintenance cycle review of these measures expected by the end of 2019.

Another commenter recommended that measure Q271 be retained in MIPS as it intends to modify the measure specification rationale, as recommended by CMS, to address the concern that the measure does not account for patients with risk factors. Due to this feedback, the commenter has expanded the rationale section of the measure specification as requested to include guidance on appropriate use of DXA scans for high-risk IBD patients and will submit these changes during the next measure maintenance cycle. As a result, the commenter requested that the measure remain in MIPS until the measure can be updated.

Response: We thank the commenter for their comment and disagree with delaying removal of measure Q271. We have reviewed the revisions proposed by the measure steward for MIPS 2020 implementation. Based on our interpretation, the revised measure's quality action would be simplified to prescribing supplements such as calcium and/or vitamin D optimization. Additionally, the measure steward proposed to replace the term "Loss Assessment" with "Health Optimization" throughout the measure, define the patient population as 18 and over, as well as updating the numerator definition to "Documentation that calcium and/or Vitamin D optimization has been ordered or performed. This includes, but is not limited to, checking serum levels, documenting use of supplements or prescribing supplements" to better align with the measure's intent. The current measure requires a Central Dual-energy X-Ray Absorptiometry (DXA) and documented review of systems and medication history or pharmacologic therapy (other than minerals/vitamins) for osteoporosis prescribed within the past two years. We agree that patients without risk factors would

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not be appropriate for frequent DXA scans as the current quality measure requires. The measure steward's substantive changes for the measure do not account for patients with high risk factors, which may warrant additional screening and pharmacologic treatment. The measure would be more robust if it was revised to assess based on multiple clinical criteria such as age, risk factors, etc. as recommended by CMS. We encourage the commenter to collaborate with the measure steward to submit a new measure during the Call for Measures process that is more robust and takes into account risk factors and require the appropriate clinical action. We thank the second commenter for their comment regarding future revisions, however, we would remind them that for the 2020 performance period the measure would not account for all clinical criteria and may not require the most appropriate clinical action. We encourage the commenter to work with measure steward to update all aspects of the measure to reflect applicable clinical quality actions for each patient population and submit to the Call for Measures once it is fully tested at the clinician level.

Comment: One commenter did not support removal of measure Q282: Dementia Functional Status Assessment, stating that the proposed duplicative measure: Q182: Functional Outcome Assessment focuses on use of physical therapy tools and as such is not applicable to this patient population. The commenter evaluated integration of measure Q182 into its QCDR in 2020 and felt given the restrictive slate of available tools, that it could not be broadly used by neurology clinicians. The commenter remains committed to measure harmonization and expanded the denominator to include physical therapy and occupational therapy as a result.

Another commenter opposed removal of measure Q282 because the measure is specific to patients with dementia and captures the percentage of patients for whom an assessment of functional status was performed at least once in the last 12 months. Measure Q182 includes patients aged 18 years and older and requires more frequent assessment and a plan of care. Also, the commenter did not believe that measure Q182 was duplicative to Q282.

Another commenter did support the removal of measure Q282, stating that the proposed duplicative measure Q182 focuses on the use of physical therapy tools and as such is not applicable to this patient population.

Response: We thank the commenter for their concern and would refer them to the measure specification which provides examples of tools for functional outcome assessment, but are not exhaustive and allow eligible clinicians to select any functional normed and validated tool. However, the proposed addition of mental/behavioral health coding to measure Q182 is not being finalized because the testing has not been completed. As a result, we are not finalizing the removal of measure Q282 from MIPS and will finalize the substantive change for this measure outlined in the 2020 PFS proposed rule (84 FR 41171) shown under Table D.79 of this final rule. Additionally, as we are not finalizing measure Q282 for removal, we will no longer be adding measure Q182: Functional Outcome Assessment to the Neurology, Geriatrics, and Mental/Behavioral Health sets as this was only proposed as a replacement measure.

Comment: One commenter did not support the removal of measure Q288: Dementia Education and Support of Caregivers for Patients with Dementia. CMS indicated there is overlap with measure Q286: Dementia: Safety Concern Screening and Follow-up for Patients with Dementia; however, the commenter stated that the measure numerators are substantially different, warranting use of both measures in MIPS. Measure Q286 is intended to ensure appropriate follow-up was taken to remove and address patient concerns that may lead to unintended injury of patients and caregivers. Measure Q288 is intended to address the unique mental health and burdens faced by caregivers for patients with dementia who are more at risk for their own mental health issues as a result of caring for patients.

Response: We thank the commenter for their comment and agree that by removing measure Q288 there may be gap in care for the dementia patient population. The health of a caregiver may directly impact the health of the patient and this may be missed in the quality action within measure Q286. As a result, we are not finalizing the removal of measure Q288 and will finalize the substantive change for this measure outlined in the 2020 PFS proposed rule (84 FR 41171) shown under Table D.80 of this final rule.

Comment: One commenter was concerned by the proposed removal of measure Q325: Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions from the MIPS program and therefore from the Mental/Behavioral Health set. As the steward of this measure, its clinical experts are responsible for the oversight of quality measures and maintain this measure's importance in assuring the delivery of high-quality care for those with MDD and medical comorbidities. The commenter understood the rationale for the measure's proposed removal and will work with its measure development team and clinical experts to determine whether this is a minimal change to the measure's technical specifications, or if this will require a more substantive update.

The commenter disagreed with the assertion that this measure is duplicative to Q374: Closing the Referral Loop: Receipt of Specialist Report. To meet Q374's numerator, a referral must occur. Without a referral, a report is not sent, no matter the reason for the encounter. Further, measure Q374 is strictly applicable to the initial encounter. In contrast, measure Q325 is intended to capture communication regarding patients treated for MDD and a comorbid condition over time.

Response: We thank the commenter for their concern regarding the removal of measure Q325. We believe, based on stakeholder's feedback, as outlined in the removal rationale, that measure Q325 is burdensome to find and review the reports sent by the MDD treating clinician, Therefore, the physician treating the co-morbid condition may not be looking for, aware of, and/or considering the patient's MDD status. Though we agree that this is an important topic, we do not believe that the quality action ensures coordination of care. Measure Q374 does need to have a referral associated with it, but ensures that there is receipt of the report, ensuring that the clinician treating the comorbid condition has received the specialist report. We encourage the commenter to submit a revised measure to the Call for Measures that addresses clinician burden while also ensuring the quality action assesses complete care coordination between clinicians.

Comment: Two commenters requested that CMS maintain four nephrology measures to promote better care coordination and alignment among the providers caring for patients receiving dialysis: measures Q328 Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin (Hgb) Level < 10 g/dL, Q329 Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis, measure Q330 Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days, and measure Q403: Adult Kidney Disease: Referral to Hospice. To advance the quality of care for patients with kidney disease, it is critical that nephrologists are measured by specific, relevant, and clinically meaningful measures.

Regarding measure Q328, anemia management is a critical component of managing the care for patients with kidney failure. Consistent with the comments submitted on the ESRD QIP on August 30, 2019, the commenter supported using a Hgb < 10 g/dL measure for dialysis facilities and, thus, called on CMS to use a similar measure for nephrologists. Regarding measure Q329, the use of catheters increases the risk of infection, morbidity, mortality, hospitalizations, and readmission. The ESRD QIP contains a similar measure to reduce the use of catheters in dialysis patients. Therefore, to coordinate the care among facilities and nephrologists, it is important to maintain this measure as measure Q330 is designed to be paired with Q329. Regarding measure Q403, a nephrologist is best positioned to work with the patient and through shared decision-making determine whether hospice is an appropriate option. Measure Q403 is also directly linked to the meaningful measure area

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of End of Life Care According to Preferences. It seems inappropriate to eliminate measures that more closely align with those used in the ESRD QIP in favor of primary care measures that are not aligned.

Response: We thank the commenters for their comments and agree that care coordination for patients receiving dialysis is important; however, measures Q328, Q329, Q330, and Q403 have limited adoption over multiple programs years, this has not allowed for the creation of benchmarks that provide a meaningful impact to quality improvement. We believe that low reported measures are an indicator of measure concepts that do not provide meaningful measurement to most clinicians. Additionally, measures that do not meet benchmarking criteria do not allow for MIPS eligible clinicians to maximize their potential quality performance score. We continue to work with measure stewards to implement measures applicable to the nephrology specialty and plan to gather stakeholder feedback at the next MAP meeting.

Comment: One multi-society commenter requested that measure Q343: Screening Colonoscopy Adenoma Detection Rate (ADR) remain in MIPS until meaningful alternatives can be developed. The adenoma detection rate is the best-established colorectal neoplasia-related quality indicator available The measure as specified accounts for a heterogeneous population of patients and purposely excludes patients at higher (prior history of polyps or cancer) risk of adenoma. The commenter failed to see how the current measure cannot be benchmarked, stating that that an adenoma detection rate of 25 percent is considered the floor, not the ceiling, by gastroenterologists. The commenter is also unaware of any studies demonstrating a relationship between adenoma detection rate and patient population. The only measure that may capture missed adenomas is a measure relative to interval cancer rate, which is not feasible to calculate for an individual clinician given the progression from adenomatous polyp to cancer occurs over an estimated 5 to 10 years in average-risk populations, lack of interoperability among electronic medical records, and patient migration. Measure Q343 establishes the framework for the Screening/Surveillance Colonoscopy episode-based cost measure such that, if removed, its absence would have unintended consequences across multiple programs.

Another commenter requested that measure Q343 not be removed from the MIPS program until the CQMC has completed its maintenance cycle review of this measure expected by the end of 2019. Another commenter opposed the removal of measure Q343 given ADR's well-established role in gastroenterology practices' quality improvement programs nationwide and the proposal to introduce MVPs.

Response: We thank the commenters, but disagree as measure Q343 is considered an incidence measure that does not assess the quality of the care provided. In essence, the measure is based on happenstance rather than the eligible clinician providing a thorough examination. The numerator is capturing the rate of adenoma(s) or colorectal cancer. Based on the measure specification's rationale "performance targets for adenoma detection rate of 25 percent for a mixed gender population (20 percent in women and 30 percent in men)." Under the current MIPS scoring methodology, a MIPS eligible clinician with a 90 percent performance rate would score higher than those that fall near the benchmark set by expert consensus. We agree with the comment that an alternative measure that addresses the scoring and benchmarking challenges should be developed. However, we do not agree that measure Q343 should be maintained in the interim.

According to the risk factors outlined by the American Cancer Society, African Americans have the highest colorectal cancer incidence and mortality rates of all racial groups in the US. In addition, dietary factors, such as consumption of highly processed meats will contribute to an increased risk of colorectal cancer. This diet is more prevalent in lower socioeconomic areas which could influence the outcome of the measure. There are other patient factors like education, health literacy, etc. that might also affect things like the adequacy of bowel preparation, which in turn could affect performance. We refer the commenter to review the response for measure Q185 as we are not finalizing the removal of the measure based on further communication with the measure steward. Lastly, in response to the inclusion of this measure within Core Quality Measures Collaborative, we have determined this measure may be appropriate for other programs, but does not align with the scoring logic within MIPS. When this measure was introduced, it was under the legacy program, Physician Quality Reporting System (PQRS). PQRS was a pay-for-reporting program which did not have the same scoring implications as MIPS transitioned to pay-for-performance.

Comment: One commenter supported the removal of two measures impacting the neurosurgical specialty because they are duplicative of other measures in the program. The commenter agreed that measure Q345: Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive is duplicative in concept and patient population to measure Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients without Major Complications (Discharged to Home by Post -Operative Day #2).

The commenter also agreed that measure Q346: Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive is duplicative in concept and patient population to measure Q260: Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post -Operative Day #2). If measures Q345 and Q346 are removed from the Neurosurgical set due to removal from the MIPS program, the commenter requested that measures Q344 and Q260 be added to the Neurosurgical set as their replacements.

Response: We thank the commenter supporting the removal of measures Q345 and Q346. We are unable to include measures Q344 and Q260 in the Neurosurgical set at this time as they were not proposed to be added, but encourage the commenter to submit their recommendations during the Call for Specialty Measure Sets.

Comment: One commenter opposed the removal of measure Q353: Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report, which was proposed for removal because CMS said it is considered standard of care that has limited opportunity to improve clinical outcomes. The commenter encouraged CMS to retain this measure, as it encourages the provision of valuable data in the total knee replacement operative report. Another commenter opposed the removal of measure Q353, stating that this measure includes valuable data on the specific types of implants, which is relevant to tracking patient outcomes. Further, as physicians routinely report registry data, the commenter did not believe reporting of this measure contributes to physician burden.

Response: As the performance on measure Q353 is extremely high and unvarying, it does not allow meaningful benchmarks to be established. By removing measures that are extremely topped out, we are attempting to reduce reporting burden where there is little room for improvement. Additionally, this allows eligible clinicians to maximize their potential quality performance score as this measures' topped out status would limit the score awarded per the 2019 Benchmark File. Removing this measure does not preclude clinicians from documenting this information and using it for their tracking purposes in regard to patient outcomes. However, given the topped out status of this measure, keeping the measure in the program does not align with the Meaningful Measure initiative.

Comment: Several commenters did not support removal of measure Q371: Depression Utilization of the PHQ-9 Tool as removal of measure Q371 would disincentivize providers from collecting PHQ-9 data. Allowing clinicians to continue to report on measure Q371 allows clinicians to integrate patient reported outcome data incrementally, driving improvement over time that might not be demonstrable in first year performance of an outcome measure. It is essential to incentivize use of

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measures such as the PHQ-9 on a regular basis. The PHQ-9 also includes a question related to suicidal ideas, which is an important element of assessment, independent of whether an individual meets other criteria for depression, particularly with the continued increase in suicide rates nationally.

Another commenter opposed the removal of measure Q371, available for eCQM reporting, as it is the most popularly reported measure with its customers. The commenter noted that the measure is being removed because a similar registry reportable measure exists as an alternative to this measure. The commenter understood that outcome measures are preferred and would ask that CMS work with measure developers to create an outcome depression measure to replace this popular measure prior to its removal.

Another commenter suggested that measure Q371 be retained in addition to measure Q370. Although measure Q370 would seem to encompass measures Q371 and Q411: Depression Remission at Six Months and make them superfluous, there are significant advantages to retaining all of these measures. Given the current fragmentation of the health care delivery system, it is essential to incentivize use of measures such as the PHQ-9 on a regular basis and measure Q371 accomplishes this goal. Retaining measure Q371 will give clinicians appropriate credit for making the PHQ-9 a routine and integral part of their workflow and will foster enhanced screening for depression and suicidal ideas as well as ongoing assessments of depression severity to guide measurement-based care.

One commenter supported removal of measure Q371 and agreed that measure Q370 is a more robust outcome measure, requiring depression remission for numerator compliance.

Response: We agree that PHQ-9 is clinically useful as a tool to support eligible clinicians with assessment of depression for patients. However, we believe that for MIPS, measure Q371 is duplicative to measure Q370: Depression Remission at Twelve Months. We are actively attempting to reduce measures that are duplicative in measurement to reduce burden and support the meaningful measure initiative. We agree with the commenter that measure Q371 is a more robust measure since performance is met upon the completion of a PHQ-9 and remission of depression at twelve months. Removing measure Q411 does not preclude clinicians from administering the PHQ-9 at any point during the patient's course of treatment and does not discourage clinicians from continuing to check symptoms using the PHQ-9 at six months. According to the clinical recommendation statement found within measure Q411 "all patients should be monitored on a monthly basis for 6 to 12 months after the full resolution of symptoms" regardless of treatment length for ongoing management of depression. This, in addition to relapse being most common in the initial six months after depression remission align with retaining measure Q370 to ensure patients are still in remission at 12 months. Despite the removal of this quality measure, we believe it does not preclude the creation of clinical processes that drive positive outcomes for patients. Additionally, the duplicative measure Q370: Depression Remission at Twelve Months is offered for the eCQM specifications collection type.

We do not believe the removal of measure Q371 will disincentivize or preclude clinicians from completing PHQ-9 since this is an easily performed screening tool for depression. As stated in the clinical recommendation of measure Q371 "Clinicians should establish and maintain follow-up with patients. Appropriate, reliable follow-up is highly correlated with improved response and remission scores. It is also correlated with the improved safety and efficacy of medications and helps prevent relapse."

Comment: One commenter opposed the removal of measure Q372: Maternal Depression Screening, stating that the measure is appropriate for use in episode-based care attributed to obstetrician-gynecologists. One commenter supported the removal of measure Q372 from the eCQM measure type.

Response: We thank the commenter supporting the removal of measure Q372. We disagree with the commenter as the denominator is constructed to assess maternal depression screening during a child's face-to-face visit in the first six months of life. This visit would be provided by the pediatric or family medicine specialty and not attributed to the obstetrician-gynecologists. During this visit the eligible clinician would be providing care for the newborn, not focus on the maternal screening.

Comment: One commenter urged CMS to reconsider the topped-out designation for measure Q407: Appropriate Treatment of Methicillin-Susceptible *Staphylococcus aureus* (MSSA) Bacteremia. Although this measure is considered standard-of-care, the commenter believed that it is inappropriate to consider removing a quality measure that promotes the appropriate use of antibiotics at a time when antimicrobial resistance is a global health emergency. Additionally, 2019 is the first year that this measure has had a benchmark. In the upcoming 2020 MIPS performance year, revisions to the measure were approved to include patients that are diagnosed with *S. aureus* bacteremia rather than only sepsis due to MSSA. This patient population expansion may allow for a more accurate measure of performance for the appropriate treatment of MSSA bacteremia.

Response: We thank the commenter for their comment. Measure Q407 has limited adoption and the benchmark is reflective of the performance of the MIPS eligible clinicians who have chosen to report on the measure. These same MIPS eligible clinicians will likely continue to submit measure Q407 and we do not believe there will be variances in the high performing data submitted if we were to retain measure Q407. Additionally, we believe that low reported measures are an indicator of measure concepts that do not provide meaningful measurement to most clinicians.

Comment: One commenter recommended retaining measure Q411: Depression Remission at Six Months. The rationale for removing this measure quotes the American Psychiatric Association's practice guideline on treatment of patients with MDD in noting that relapse is common in the initial six months after depression remission and in providing a definition of continuation therapy. While these quotations are accurate, they do not support a rationale for removal of this measure. The measure of depression at 12 months (measure Q370) includes individuals who are seen and have a PHQ-9 completed within 30 days (+/-) of the 12-month time point. This may not capture all patients who have been treated for depression (e.g., patients seen by a psychiatrist who have remitted and then returned to their primary care physician for ongoing care).

Another commenter supported the removal of measure Q411 as it found the measure to be invalid.

Response: We thank the commenter for supporting the removal of measure Q411. We thank the other commenter for their concern regarding the removal of measure Q411. Removing measure Q411 does not preclude clinicians from administering the PHQ-9 at any point during the patient's course of treatment and does not discourage clinicians from continuing to check symptoms using the PHQ-9 at six months. According to the clinical recommendation statement found within measure Q411 "all patients should be monitored on a monthly basis for 6 to 12 months after the full resolution of symptoms" regardless of treatment length for ongoing management of depression. This, in addition to relapse being most common in the initial six months after depression remission align with retaining measure Q370 to ensure patients are still in remission at 12 months.

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Comment: One commenter disagreed with the removal of measure Q442: Persistence of Beta-Blocker Treatment After a Heart Attack by replacing the measure with Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%). Measure Q442 assesses whether patients get persistent medication over six months; however, the proposed replacement assesses only if patients get the drug once.

Another commenter opposed not implementing the exclusion for adults 80 and older with frailty for measure Q442 (if retained in MIPS). This exclusion is critical for focusing the measures on the population most likely to benefit from the measured services. Without this exclusion, these measures will be out of alignment with what is required for reporting. Another commenter believed that measure Q442 should not be removed, stating that it is a valid measure and is based on high-quality evidence from multiple specialty organizations, while another commenter requested that the measure be retained until the CQMC has completed its maintenance cycle review of this measure expected by the end of 2019.

Response: We disagree with the commenters as measure Q007 is reflective of beta-blocker use and overlaps with the population of patients captured within the denominator of measure Q442. Measure Q442 focuses the denominator on those patients that have experienced acute myocardial infarction which is narrower than Measure Q007. Additionally, the numerator in measure Q442 requiring six months of medication compliance further narrows the denominator to the first six months of the performance period. The denominator in measure Q007 represents a broader patient population and may be evaluated throughout the entirety of the performance period. Therefore measure Q007 represents a more robust measure that supports the meaningful measure initiative. As we are finalizing removal of this measure, we will not be implementing the substantive change for this measure outlined in 84 FR 41180.

Comment: One commenter opposed the removal of measure Q449: HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies. This measure would have a substantive change if the measure is not finalized for removal, and the commenter stated that the measure has had substantive changes due to updates in recent guidelines and given that it is not possible to know whether the measure is topped out under these circumstances, the commenter recommended measure Q449 be retained in the MIPS program.

Response: We thank the commenter for their comment, but do not believe that the change in current clinical guidelines will change performance rates in the measure. We believe that eligible clinicians will most likely quickly update their practice in the treatment of breast cancer to support quality outcomes with these patients based on the new clinical guidelines. We encourage the measure steward to collect performance data based on the updated guidelines, in the event it substantiates a performance gap, a new measure could be submitted to the Call for Measures.

Comment: One commenter opposed the removal of measure Q454: Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better). The commenter stated that the evidence supports existence of a significant gap and variation in care related to the measure. For patients with cancer at the end of life, the use of unnecessary services such as the emergency department can negatively impact a patient and family's quality of life and satisfaction with end of life care. Emergency department visits in the last 30 days of life are one indicator that supportive care may not be provided effectively to these patients.

Response: We thank the commenter for their comment and agree that end of life care and care coordination for patients with cancer is important to assess, however, we believe that this may be outside of the eligible clinician's control. We believe that measure Q455: Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better) is more indicative of the supportive care provided and its efficacy as admittance to the ICU would be based on clinical factors and not the patient's decision. It is also likely that many of the patients within the eligible population for measure Q455 were admitted to the ICU through the emergency department, meaning this population would be accounted for in multiple measures.

Comment: One commenter opposed the removal of measure Q456: Percentage of Patients who Died from Cancer Not Admitted to Hospice (lower score – better). The commenter stated that although the use of hospice and other palliative care services at the end of life has increased, many patients are enrolled in hospice less than three weeks before their death, which limits the benefit they may gain from these services. There remains significant value and demonstration of quality care in ensuring a low percentage of patients dying from cancer who are not receiving hospice care through this measure. For these reasons, the commenter requested that measure Q456 be retained in the MIPS program.

Response: We thank the commenter for their comment and agree that increasing hospice utilization in cancer patients is important. We believe that measure Q457 is a better indicator of hospice usage as it has a more stringent numerator by assessing the number of patients who spent less than three days in hospice whereas measure Q456 assesses all patients not admitted to hospice, allowing patients admitted to hospice less than three days to be Performance Not Met (representing better clinical quality as this in an inverse measure).

Comment: One commenter recommended that CMS delay removing measure Q467: Developmental Screening in the First Three Years of Life measures from the MIPS program until the CQMC has completed its maintenance cycle review of these measures expected by the end of 2019.

Response: We thank the commenter for their comment and disagree with delaying removal of measure Q467. The measure steward submitted a substantive change that would expand the denominator to include well-child visits. The well-child visit encounters would likely include the attestation of screening for risk of developmental, behavioral, and social delays using a standardized tool, which is the quality action for measure Q467, thereby inflating performance of the measure. This would lead to a less meaningful assessment for MIPS eligible clinicians.

Comment: One commenter supported the removal of measure Q474: Zoster (Shingles) Vaccination as it found the measure to be invalid.

Response: We thank the commenter for supporting the removal of measure Q474.

After consideration of the comments, we are finalizing the removal of these measures as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the exception of the following measures, which are being retained: Q110, Q111, Q146, Q178, Q185, Q225, Q249, Q250, Q264, Q282, Q288, Q395, and Q396. Our decisions not to finalize these measures for removal in this final rule are detailed in our responses to the public comments for these measures. We are also finalizing substantive changes for measures Q110, Q111, Q178, Q282, and Q288 (See Tables D.79, D.80, D.81, D.82, and D.83).

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Finalized for the 2022 MIPS Payment Year and Future Years

NOTE: Electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table D as follows: NQF # / eCQM NQF #.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.
Substantive Change:	**Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days during the measurement period. **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might be harmful for patients to receive a particular service when they should prioritize other services. The measure steward also believes that some of the services in this measure are not appropriate for patients 66 years of age and older who are living in a long-term institutional setting. We agree with the measure steward and believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians.

Comment: One commenter supported the proposed changes to measure Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%). Another commenter reviewed the proposed changes to the CMS Web Interface Measure Specification collection type for measure Q001 and believed there are impacts to the benchmarks and a need to provide pay-for-reporting for 2019 and 2020 MIPS performance periods.

Response: We thank the commenter for supporting the revision to measure Q001. Under MIPS, there is no pay-for-reporting option. In these instances, we exclude the measure from MIPS scoring for the CMS Web Interface Measure Specification collection type in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement for the impacted performance period. For this substantive change, we disagree with the second commenter that the measure should be excluded from MIPS scoring for the 2019 MIPS performance period as these revisions will be implemented for the 2020 MIPS performance period and do not affect the 2019 MIPS performance period. Additionally, we do not believe that the revisions necessitate an updated benchmark for the MIPS 2020 performance period as the updated denominator exclusions do not significantly change the patient population, but work to create a more relevant patient population for the quality action, which remains unchanged.

Comment: One commenter supported the denominator exclusions added for frailty for ACO-27 (measure Q001): Diabetes A1c Poor Control. The commenter also requested that the age restriction is removed from these exclusions, as many of these interventions are not clinically appropriate in those with frailty and limited life expectancy due to advanced illness, regardless of age.

Response: We thank the commenter for supporting the revision to measure Q001. We encourage the commenter to reach out to the measure steward and collaborate regarding further refinement of the denominator exclusions.

For the eCQM Specifications collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

Updated denominator exclusions: For eCQM Specifications collection type: Added the following:
(1) Exclude patients 66 and older who are living long term in an institution for more than 90 days during the measurement period.
(2) Exclude patients 66 and older with advanced illness and frailty because it is unlikely that patients will benefit from the services being measured.

Category	Description
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified for measure Q001 and does not affect the intent of the proposed substantive change. For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state: **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 days during the measurement period This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified and to decrease clinician burden by outlining the coding for the denominator exclusion for measure Q001 and does not affect the intent of the proposed substantive change. There were no additional refinements to substantive changes: **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following; (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine After consideration of the comments, we are finalizing the changes as indicated to measure Q001 for the 2020 MIPS performance period/2022 MIPS payment year and future years with the refinements noted above.	

D.2. Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality #:	005
CMS eCQM ID:	CMS135v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**The measure title is revised to read:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD). **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12- month period when seen in the outpatient setting OR at each hospital discharge. **Updated denominator:** For the MIPS CQMs Specifications collection type for Submission Criteria 1 – "At least on additional patient encounter during performance period", telehealth encounters will be included as denominator eligible encounters. **Updated numerator:** Added language for ARNI therapy. **Updated definition:** Added language for ARNI therapy.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	This measure already includes ARNI therapy in the specifications and coding as well as a statement about the fact that ARNIs are a numerator compliant clinical action. The measure was proposed to be globally updated to include ARNI therapy language in the title, description, numerator, definition, denominator exception, and rate aggregation to align with the intent of the measure. With the inclusion of ARNI therapy, the intent of this measure is aligned with the most current clinical guidelines for ACE/ARB therapies for patient's diagnoses with heart failure. Telehealth visits, for the additional denominator eligible encounters, were added for Submission Criteria 1 in the MIPS CQMs Specifications collection type.
We received no comments on the substantive changes proposed for measure Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD). Therefore, we are finalizing the changes to measure Q005 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.3. Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0070 / 0070e
Quality #:	007
CMS eCQM ID:	CMS145v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI or a current or prior LVEF < 40 percent who were prescribed beta-blocker therapy.
Substantive Change:	**Updated calculation method:** For the MIPS CQMs Specifications collection type: To be submitted as a single performance rate. **Updated denominator:** For the MIPS CQMs Specifications collection type, "At least one additional patient encounter during performance period", telehealth encounters will be included as denominator eligible encounters.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure performance calculation for the MIPS CQMs Specifications collection type so that it is submitted as a single performance rate as opposed to two performance rates. This change allows for better alignment between the collection types. We also proposed to add telehealth visits for the additional denominator eligible encounters for the MIPS CQMs Specifications collection type. This change is in alignment with the eCQM Specifications collection type. We believe these changes will allow for data congruency between the collection types while also lessening burden for implementation of the measure across these collection types.
We received no comments on the substantive changes proposed for measure Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%). Therefore, we are finalizing the changes to measure Q007 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.4. Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality #:	008
CMS eCQM ID:	CMS144v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**For the eCQM Specifications collection type:** The timing for cardiac pacer in situ diagnosis logic has been changed to 'overlaps after'. **Updated denominator: For the MIPS CQMs Specifications collection type**: For Submission Criteria 1, "At least one additional patient encounter during performance period", telehealth encounters will be included as denominator eligible encounters.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	For the eCQM Specifications collection type: the logic regarding the cardiac pacer in situ diagnosis was proposed to be updated to change the timing to 'overlaps after' to ensure it is present at the time of the end of the encounter and for harmonization with CMS145v8. For the MIPS CQMs Specifications collection type: we proposed to add telehealth encounters for the additional patient encounter as denominator eligible encounters for Submission Criteria 1. This change is in alignment with the eCQM Specifications collection type. We believe these changes will allow for data congruency between the collection types while also lessening burden for implementation of the measure across these collection types.
Comment: One commenter supported proposed revisions to measure Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) that would add in telehealth encounters to be included as eligible encounters. **Response:** We thank the commenter for supporting the revision to measure Q008. After consideration of the comments, we are finalizing the changes to measure Q008 as proposed for the 2020 MIPS performance period/2022 MIIPS payment year and future years.	

D.5. Anti-Depressant Medication Management

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	009
CMS eCQM ID:	CMS128v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Substantive Change:	**Updated guidance:** Guidance statement updated to reflect the 105 day negative medication history. **Updated denominator:** The required visit needs to be in the 60 days before or after the initial patient population antidepressant medication dispensing event. The initial patient population dispensing period will be from May 1st of the year prior to the measurement period to April 30th of the measurement period. Added nursing home encounters to list of qualifying encounters. **Updated denominator exclusion:** Changed timing to 'overlaps' so that medications that are active in the 105 days prior may count.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to expand the denominator to include nursing home encounters as this measure is applicable to that setting and this will increase the number of MIPS eligible clinicians who can report on the measure. The required visit for the initial patient population is proposed to be in the 60 days before or after the initial patient population antidepressant medication dispensing event as the intent is for a physician who has influence over the medication choice and follow-up to report the measure. The measure steward feels, and we agree, that associating the visit with the medication dispensing event is more in line with the intent of the measure. The initial patient population dispensing period is also being updated. We proposed to update the denominator exclusion logic so that medications that are active in the 105 days prior will also count as an exclusion. We proposed to update the guidance as well to reflect the change in the denominator exclusion.
We received no comments on the substantive changes proposed for measure Q009: Anti-Depressant Medication Management. Therefore, we are finalizing the changes to measure Q009 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.6. Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	0089 / 0089e
Quality #:	019
CMS eCQM ID:	CMS142v8
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as the benchmarking data shows that this measure meets the extremely topped out definition, specifically for the Medicare Part B Claims Measure Specification collection type. However, the benchmarking data continues to show a gap for the eCQM Specifications collection type and the MIPS CQMs Specifications collection type, as such, the measure will be retained for these two collection types.
Comment: One commenter opposed the removal of the Medicare Part B Claims Measure Specifications collection type for measure Q019: Diabetic Retinopathy: Communication with Physician Managing Ongoing Diabetes Care. The commenter encouraged CMS to retain this collection type, because its removal from the measure would adversely impact ophthalmologists, particularly those in small and rural practices that rely on claims reporting because they cannot afford to adopt CEHRT. Removing this collection type would result in an even fewer measures relevant to ophthalmologists' scope of practice. A second commenter opposed this change and recommended that CMS retain the measure and increase the data completeness criteria as the Agency discusses as a possible way forward for topped out measures. **Response:** We appreciate the commenter's feedback and disagree that removal of measure Q019 from the Medicare Part B Claims collection type will adversely impact ophthalmologists. Clinicians who elect to participate via Medicare Part B claims collection type, and choose to submit extremely topped out measures, are penalized in their quality score under current methods by receiving a maximum of 7 of 10 points for each topped out measure; therefore clinicians may not have an opportunity to maximize incentive with the submission of topped out measures. CMS encourages the commenter to explore other collection types such as Qualified Registries or QCDRs in order to submit measures to CMS. After consideration of the comments, we are finalizing the changes to measure Q019 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.7. Appropriate Testing for Children with Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	066
CMS eCQM ID:	CMS146v8
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.
Substantive Change:	**Updated numerator: For the eCQM Specifications collection type:** Removed Ambulatory/ED grouping value set, instead using the individual value sets. **Updated denominator exclusions:** Added exclusion for competing diagnosis at the same encounter as the pharyngitis diagnosis or in the 3 days after the pharyngitis diagnosis.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	For the eCQM Specifications collection type: The Ambulatory/ED grouping value sets were proposed to be removed so that individual value sets will be used in order to increase transparency regarding which encounter value set is being utilized. A denominator exclusion for a competing diagnosis that occurs at the same encounter or 3 days after the pharyngitis diagnosis was proposed to be added to ensure the patient population being assessed is more in alignment with clinical intent of assessing whether or not children diagnosed with pharyngitis were correctly evaluated and subsequently ordered antibiotics.
We received no comments on the substantive changes proposed for measure Q066: Appropriate Testing for Children with Pharyngitis. Therefore, we are finalizing the changes to measure Q066 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.8. Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections

Category	Description
NQF # / eCQM NQF #:	2726
Quality #:	076
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.
Substantive Change:	**Updated numerator definition:** Added definition for Hand Hygiene: Washing hands with conventional soap and water or with alcohol-based hand rubs (ABHR).
Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add the definition for hand hygiene that is found in the Clinical Recommendation Statement as a numerator definition to make it more prominent and add clarity for measure users.
Comment: One commenter supported the updated definition of Hand Hygiene, which has been added to measure Q076: Prevention of Central Venous Catheter (CVC) – Related Bloodstream Infections through the NQF measure maintenance process. **Response:** We thank the commenter for supporting the revision to measure Q076, however, we would like to remind the commenter that this revision occurred during MIPS annual quality measure revision process and not the NQF measure maintenance process. After consideration of the comments, we are finalizing the changes to measure Q076 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.9. Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients

Category	Description
NQF # / eCQM NQF #:	0389 / 0389e
Quality #:	102
CMS eCQM ID:	CMS129v9
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer. **Updated denominator:** Removed cryotherapy from denominator statement/header. **Updated denominator definition:** Removed "Note: Patients with multiple adverse factors may be shifted into the high/very high risk category" from definition of Intermediate Risk. **For the eCQM Specifications collection type:** removed SNOMED and CPT codes related to cryotherapy from the SNOMED CT extensional OID and CPT extensional OID "Prostate Cancer Treatment" value set.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove cryotherapy from the measure to align with updated clinical guidelines. Current clinical guidelines do not recommend cryotherapy as a routine primary therapy for localized prostate cancer due to the lack of long-term data comparing this to treatments such as radiation or radical prostatectomy. Given that the denominator includes treatments recommended for low/very low-risk prostate cancer patients, the measure steward's technical expert panel (TEP) agreed cryotherapy should be removed from the denominator. All coding related to cryotherapy is being removed in accordance with the updated guidelines. We proposed to update the denominator definition to align with updated guidelines.
We received no comments on the substantive changes proposed for measure Q102: Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients. Therefore, we are finalizing the changes to measure Q102 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.10. Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	0104e
Quality #:	107
CMS eCQM ID:	CMS161v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.
Substantive Change:	**Updated denominator:** Added telehealth data element to "Major Depressive Disorder Encounter" definition using "Telehealth Services" value set. **Updated guidance:** Updated to reflect the inclusion of telehealth encounters. **Updated definition:** The specific type and magnitude of the suicide risk assessment is intended to be at the discretion of the individual clinician and should be specific to the needs of the patient. At a minimum, suicide risk assessment should evaluate: (1) Suicidal ideation (2) Patient's intent of initiating a suicide attempt AND, if either is present, (3) Patient plans for a suicide attempt (4) Whether the patient has means for completing suicide Low burden tools to track suicidal ideation and behavior such as the Columbia-Suicide Severity Rating Scale (C-SSRS) and the Suicide Assessment Five-Step Evaluation and Triage (SAFE-T) can also be used. Because no validated assessment tool or instrument fully meets the aforementioned requirements for the suicide risk assessment, individual tools or instruments have not been explicitly included in coding.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure was reviewed by PCPI's technical expert panel and it was recommended to include telehealth encounters. We proposed to add telehealth data element to "Major Depressive Disorder Encounter" as telehealth encounters are directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We proposed to reflect this change in the guidance header for additional clarity. We proposed to add clarifying language in the definition header regarding suicide risk assessments that could be appropriate to meet the measure. It is still intended that the MIPS eligible clinician use their discretion when choosing the specific type and magnitude of the suicide risk assessment, based upon the patient's specific needs, but the suicide risk assessments should include, at minimum, certain criteria.

Comment: One commenter supported proposed revisions to measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment that would add in telehealth encounters to be included as eligible encounters.

Response: We thank the commenter for supporting the revision to measure Q107.

After consideration of the comments, we are finalizing the changes to measure Q107 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.

D.11. Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.
Substantive Change:	**The measure description is revised to read:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period. **The numerator is revised to read:** Women with one or more mammograms 27 months prior to the end of the measurement period. **Updated denominator exclusions: For eCQM Specifications collection type:** (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days during the measurement **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator guidance: For the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications collection types**: Added "This measure evaluates primary screening. Do not count biopsies, breast ultrasounds, or MRIs because they are not appropriate methods for primary breast cancer screening. Mammography screening is defined as a bilateral screening (both breasts) of breast tissue. If only one breast is present, unilateral screening (one side) must be performed on the remaining breast."
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a timing component to the description for better clarity and alignment throughout the measure. The numerator was revised to state the timing in the same manner as the description, however, the timing itself has not been changed only stated differently. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services. The measure steward also believes that some of the services in this measure are not appropriate for patients 66 years of age and older who are living in a long-term institutional setting. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians. We proposed to update the numerator guidance for the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection types to clarify the intent of the measure. The measure logic for the Medicare Part B Claims Measure Specifications will remain the same from prior years to allow a 27-month look back from the denominator eligible visit.

Category	Description

Comment: One commenter supported the denominator exclusions added for frailty for ACO-20 (measure Q112): Breast Cancer Screening. The commenter also requested that the age restriction be removed from these exclusions, as many of these interventions are not clinically appropriate in those with frailty and limited life expectancy due to advanced illness, regardless of age. The commenter recommended the following exclusion: Remove age restriction (below 65 years of age) for exclusion in a Long-Term Care Setting.
Response: We thank the commenter for supporting the revision of measure Q112. We encourage the commenter to reach out to the measure steward and collaborate regarding further refinement of the denominator exclusions.

Comment: One commenter reviewed the proposed changes to the CMS Web Interface Measure Specification collection type for measure Q112 and believed there are impacts to the benchmarks and a need to provide pay-for-reporting for the 2019 and 2020 MIPS performance periods.

Response: We thank the commenter for their comment. Under MIPS, there is no pay-for-reporting option. In these instances, we exclude the measure from MIPS scoring for the CMS Web Interface Measure Specification collection type in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement for the impacted performance period. For these substantive changes, we disagree with the commenter that the measure should be excluded from MIPS scoring for the 2019 MIPS performance period as these revisions will be implemented for the 2020 MIPS performance period and do not affect the 2019 MIPS performance period. Additionally, we do not believe that the revisions necessitate an updated benchmark for the MIPS 2020 performance period as the updated denominator exclusions do not significantly change the patient population, but work to create a more relevant patient population for the quality action, which remains unchanged. All other updates were for language alignment and clarity of intent and therefore would not necessitate exclusion from MIPS scoring.

For the eCQM Specifications collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

Updated denominator exclusions: For eCQM Specifications collection type:
(1) Exclude patients 66 and older who are living long term in an institution for more than 90 days during the measurement period.
(2) Exclude patients 66 and older with advanced illness and frailty because it is unlikely that patients will benefit from the services being measured.
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified for measure Q112 and does not affect the intent of the proposed substantive change.
For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:
Added the following:
(1) Patient age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code 32, 33, 34, 54, or 56 for more than 90 days during the measurement period.

This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified and to decrease clinician burden by outlining the coding for the denominator exclusion for measure Q112 and does not affect the intent of the proposed substantive change.
We proposed a substantive change to the numerator; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

The numerator is revised to read: Women with one or more mammograms during the 27 months prior to the end of the measurement period. This additional refinement does not affect the intent of the proposed substantive change.

This additional refinement was to ensure clarity in language for measure Q112 and does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
The measure description is revised to read: Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.

For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:
Added the following:
(2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period.
(3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period.
(4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine
Miscellaneous central nervous system agents: Memantine

Updated numerator guidance: For the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications collection types: Added "This measure evaluates primary screening. Do not count biopsies, breast ultrasounds, or MRIs because they are not appropriate methods for primary breast cancer screening. Mammography screening is defined as a bilateral screening (both breasts) of breast tissue. If only one breast is present, unilateral screening (one side) must be performed on the remaining breast."

After consideration of the comments, we are finalizing the changes to measure Q112 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the refinements noted above.

D.12. Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients aged 66 years and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator guidance: For Medicare Part B Claims Measure Specification and MIPS CQMs Specifications collection types:** Do not count DRE, FOBT tests performed in an office setting or performed on a sample collected via DRE.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add denominator exclusions for patients aged 66 years and older with advanced illness and frailty, taking certain dementia medications, or who are living in a long-term institutional setting for more than 90 days. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services. The measure steward believes the measure reflects services that may not be appropriate for patients in long-term institutional settings. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians. We also proposed to update guidance for numerator compliance for the Medicare Part B Claims Measure Specification and MIPS CQMs Specifications collection types to align with eCQM Specifications and CMS Web Interface Measure Specifications collection types. The update would not allow fecal occult blood test (FOBT) via tests performed in an office setting or performed on a sample collected via DRE to be numerator compliant. This update aligns with a more effective method as FOBT by stool passed spontaneously (SPS) appears to be statistically superior to FOBT by DRE. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

Category	Description

Comment: One commenter reviewed the proposed changes to the CMS Web Interface Measure Specification collection type for measure Q113 (PREV-6): Colorectal Cancer Screening and believed there are impacts to the benchmarks and a need to provide pay-for-reporting for 2019 and 2020 MIPS performance periods.

Response: We thank the commenter for their comment. Under MIPS, there is no pay-for-reporting option. In these instances, we exclude the measure from MIPS scoring for the CMS Web Interface Measure Specification collection type in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement for the impacted performance period. However, this measure will maintain its current benchmark for the CMS Web Interface Measure Specification collection type for the 2019 performance period. The revisions regarding the updated guidance for DRE of FOBT proposed to Medicare Part B Claims Measure and MIPS CQMs specifications collections types were already present in the CMS Web Interface Measure specification collection type, and the updated denominator exclusions do not significantly change the patient population, but work to create a more relevant patient population for the quality action. Therefore allowing the CMS Web Interface Measure Specification collection type benchmark to remain stable for the 2020 MIPS performance period/2022 MIPS payment year. New benchmarks will be created for the Medicare Part B Claims Measure and MIPS CQMs specifications collections types for the 2020 MIPS performance period, as this revision impacts those collection types.

Comment: One commenter supported the denominator exclusions added for frailty for ACO-19 (measure Q113): Colorectal Cancer Screening. The commenter also requested that the age restriction is removed from these exclusions, as many of these interventions are not clinically appropriate in those with frailty and limited life expectancy due to advanced illness, regardless of age. The commenter recommended the following exclusion: Remove age restriction (below 65 years of age) for exclusion in a Long-Term Care Setting.

Response: We thank the commenter for supporting the revision of measure Q113. We encourage the commenter to reach out to the measure steward and collaborate regarding further refinement of the denominator exclusions.

For the eCQM Specifications collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

Updated denominator exclusions: For eCQM Specifications collection type: Added the following:
(1) Exclude patients 66 and older who are living long term in an institution for more than 90 days during the measurement period.
(2) Exclude patients 66 and older with advanced illness and frailty because it is unlikely that patients will benefit from the services being measured.
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified for measure Q113 and does not affect the intent of the proposed substantive change.

For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type: Added the following:
(1) Patient age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code 32, 33, 34, 54, or 56 for more than 90 Days during the measurement period.
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified and to decrease clinician burden by outlining the coding for the denominator exclusion for measure Q113 and does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type: Added the following:
(2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period.
(3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period.
(4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine
Miscellaneous central nervous system agents: Memantine

Updated numerator guidance: For Medicare Part B Claims Measure Specification and MIPS CQMs Specifications collection types: Do not count DRE, FOBT tests performed in an office setting or performed on a sample collected via DRE.

After consideration of the comments, we are finalizing the changes to measure Q112 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the refinements noted above.

D.13. Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period. **Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. **For Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator:** Allows use of a diagnosis of retinopathy as a proxy for a positive eye exam. • If the patient has a diagnosis of retinopathy that overlaps the measurement period, the patient will be required to have an eye exam in the measurement period. • If the patient does not have a diagnosis of retinopathy that overlaps the measurement period, the patient will be required to have an eye exam in the 24 months prior to the end of the measurement period.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description to better align with changes to logic. We agree with this update as it clarifies the intent of the measure. We proposed to add denominator exclusions for patients aged 66 years and older with advanced illness and frailty, taking certain dementia medications, and for patients who are living in a long-term institutional setting, such as a nursing home. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services and that services within this measure may not be appropriate for older patients living in a long-term institutional setting for longer than 90 days during the measurement period. In response to reports from EHR vendors that the measure was not reportable due to the results from an eye exam not being in structured data, we proposed to use the diagnosis of retinopathy as a proxy for a positive eye exam. Patients with a diagnosis of retinopathy are required to have an eye exam yearly while patients without that diagnosis are required to have an eye exam once every 24 months. We believe that by removing these two patient populations, the burden to submit data is lessened for these MIPS eligible clinicians.

Category	Description

Comment: One commenter did not support the substantive changes proposed for measure Q117: Diabetes: Eye Exam and the proposal to update the denominator exclusions and to include those individuals who are 66 and older and who are frail and those who have been living in a long-term institution setting for more than 90 days in the measurement period.

To eliminate the frail and those living in assisted living institutions from this measure is inappropriate as these patients could benefit from the type of high-quality health care that quality measurement is intended to support.

Additionally, the commenter had concerns with the proposal to update the numerator to allow for patients who do not have a diagnosis of retinopathy to be required to have an eye exam in the 24 months prior to the end of the measurement period. The commenter is concerned that this change does not fully adhere to clinical practice guidelines. The American Diabetes Association Standards of Medical Care recommend, "If there is no evidence of retinopathy for one or more annual eye exam and glycemia is well controlled, then exams every 1–2 years may be considered. If any level of diabetic retinopathy is present, subsequent dilated retinal examinations should be repeated at least annually by an ophthalmologist or optometrist. If retinopathy is progressing or sight-threatening, then examinations will be required more frequently."

Response: We thank the commenter for their concern regarding the proposed denominator exclusions for patients who are frail or living in a long-term institution setting for more than 90 days in the performance period. We understand that there may be patients within the excluded population that could benefit from these services and we are in no way precluding clinicians from performing these services. By excluding these patients, the measure is allowing clinicians to focus on aspects of care that are more immediately necessary and will have a greater impact on the patient's overall quality of life. These exclusions allow clinicians to exercise shared decision making with the patient or care-taker in determining necessary clinical care. These quality measures are not intended to be used as clinical guidelines. We will continue to work with the measure steward to ensure that we are not excluding a critical patient population. In regards to the comment about eye exam requirements, the measure as currently specified allows for the an eye exam to occur during the current measurement period or the 12 months prior to the current measurement period to be numerator compliant in the instance the patient has a negative retinal or dilated eye exam. Therefore, the timing of the quality action has not changed due to these updates in language and use of a retinopathy diagnosis as a proxy to an eye exam. We encourage the commenter to collaborate with the measure steward on revisions to be proposed for future year implementation.

For the eCQM Specifications collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

Updated denominator exclusions: For eCQM Specifications collection type: Added the following:
(1) Exclude patients 66 and older who are living long term in an institution for more than 90 days during the measurement period.
(2) Exclude patients 66 and older with advanced illness and frailty because it is unlikely that patients will benefit from the services being measured.
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified for measure Q117 and does not affect the intent of the proposed substantive change.
For Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:
(1) Patient age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code 32, 33, 34, 54, or 56 for more than 90 Days during the measurement period.
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified and to decrease clinician burden by outlining the coding for the denominator exclusion for measure Q117 and does not affect the intent of the proposed substantive change.

We proposed a substantive change to the numerator; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

Updated numerator:
Patients with an eye screening for diabetic retinal disease. This includes diabetics who had one of the following:
• Diabetic with a diagnosis of retinopathy that overlaps the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period
• Diabetic with no diagnosis of retinopathy overlapping the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period or the year prior to the measurement period
This additional refinement was to ensure clarity in language so that the clinically appropriate quality action is identified for measure Q117 and does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
The measure description is revised to read: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.

For Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection type: Added the following:
(2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period.
(3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period.
(4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine
Miscellaneous central nervous system agents: Memantine

After consideration of the comments, we are finalizing the changes as indicated to measure Q117 for the 2020 MIPS performance period/2022 MIPS payment year and future years with the refinements noted above.

D.14. Diabetes: Medical Attention for Nephropathy

Category	Description
NQF # / eCQM NQF #:	0062 / N/A
Quality #:	119
CMS eCQM ID:	CMS134v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.
Substantive Change:	**Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. **For CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add denominator exclusions for patients aged 66 years and older with advanced illness and frailty, taking certain dementia medications, and for patients who are living in a long-term institutional setting, such as a nursing home. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services and that services within this measure may not be appropriate for older patients living in a long-term institutional setting for longer than 90 days during the measurement period. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians.

For the eCQM Specifications collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

Updated denominator exclusions: For eCQM Specifications collection type: Added the following:
(1) Exclude patients 66 and older who are living long term in an institution for more than 90 days during the measurement period.
(2) Exclude patients 66 and older with advanced illness and frailty because it is unlikely that patients will benefit from the services being measured.
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified for measure Q119 and does not affect the intent of the proposed substantive change.
For CQMs Specifications collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

For CQMs Specifications collection type: Added the following:
(1) Patient age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code 32, 33, 34, 54, or 56 for More Than 90 Days during the measurement period.
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified and to decrease clinician burden by outlining the coding for the denominator exclusion for measure Q119 and does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
For CQMs Specifications collection type: Added the following:
(2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period.
(3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period.
(4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine
Miscellaneous central nervous system agents: Memantine

We received no comments on the substantive changes proposed for measure Q119: Diabetes: Medical Attention for Nephropathy. Therefore, we are finalizing the changes to measure Q119 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the refinements noted above.

D.15. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	0421 / 0421e
Quality #:	128
CMS eCQM ID:	CMS69v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.
Substantive Change:	**Updated denominator exclusions:** Added patients in hospice care. Removed "or refuse follow-up" language from denominator exclusion. **For the eCQM Specifications collection type:** Added a 'union' operator of 'Intervention, Performed' for each 'Intervention, Order' for Above and Below Normal Follow-Up Interventions, and a 'union' operator of 'Intervention, Not Performed' for each 'Intervention, Not Ordered' for Above and Below Normal Follow-up Interventions not done due to a medical reason.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward convened an expert work group (EWG) and it was recommended that patients receiving hospice care should be removed from this measure. We agree with the EWG that this patient population should be removed as patients in hospice care would not benefit from this clinical service. Since assessment of BMI is not a valuable clinical assessment for hospice patients we believe that by removing this patient population it will reduce the burden of submission for these MIPS eligible clinicians providing care to these patients. We proposed to remove "or refuse follow-up" from the denominator exclusion for clarity. We proposed to add a union operator to the eCQM Specifications collection type to allow the intervention to be either completed or ordered, creating a new numerator option. We proposed to update the eCQM Specifications collection type by adding a 'union' operator to allow intervention to be either completed or ordered for numerator compliance. This allows for better alignment with measure intent.

Comment: One commenter supported the proposed changes to measure Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan.

Response: We thank the commenter for supporting the revision to measure Q128.

After consideration of the comments, we are finalizing the changes to measure Q128 as proposed for the 2020 MPS performance period/2022 MIPS payment year and future years.

D.16. Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	0418 / 0418e
Quality #:	134
CMS eCQM ID:	CMS2v9
National Quality Strategy Domain:	Community/ Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **Updated denominator:** Added speech language pathology MIPS eligible clinician type. **For the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications:** Added physical therapy MIPS eligible clinician type. **Updated denominator exception:** Updated language to situations where the patient's cognitive capacity, functional capacity or motivation to improve may impact the accuracy of results of standardized depression assessment. **The numerator is revised to read:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **For the eCQM Specifications collection type:** Updated the "Depression medications – adolescent" and the "Additional evaluation for depression – adolescent" value sets to include additional medications.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description for better alignment with the measure intent and clinical practices, therefore the measure, will reflect those changes within the guidance and logic. This change will not affect the denominator population, but may expand the numerator population and provides a better opportunity for compliance. Based upon requests from stakeholders physical therapy evaluation codes were proposed to be add to the denominator eligible encounters to allow for this measure to be used in an additional setting. We agree that this is a clinically relevant measure to the physical therapy setting. We proposed to update the denominator exception for better clarity to allow MIPS eligible clinicians to use cognitive capacity as a denominator exception. The measure steward based this decision on feedback from clinical subject matter experts. We agree that this is not a new denominator exception, but rather clarifies what is deemed a denominator exception for this measure. The eCQM Specifications collection type's adolescent medication value sets was proposed to be updated to include additional medications based upon recommendations from clinical subject matter experts. The additions will provide an opportunity for better compliance by expanding the list of appropriate medication codes while also improving alignment with measure intent.

Category	Description
Comment: One commenter supported the addition of the physical therapy codes to measure Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan. Another commenter reviewed the proposed changes to the CMS Web Interface Measure Specification collection type for measure Q134 and questioned whether the changes impact the benchmarks but urged CMS to explore and consider whether this measure warrants pay-for-reporting for the 2019 and 2020 MIPS performance period. **Response:** We thank the commenter for supporting the revision to measure Q134. Under MIPS, there is no pay-for-reporting option. In these instances, we remove the benchmark for the CMS Web Interface Measure Specification collection type in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement for the impacted performance period. For these substantive changes, we disagree with the second commenter that the measure should be excluded from MIPS scoring for the 2019 MIPS performance period as these revisions will be implemented for the 2020 MIPS performance period and do not affect the 2019 MIPS performance period. Additionally, we do not believe that the revisions necessitate an updated benchmark for the MIPS 2020 performance period as the revision to allow the screening to occur up to 14 days prior to the encounter better aligns with clinical practices and provides a better opportunity for compliance however, the quality action being assessed has not changed. The updated denominator exception offers clarity for implementation and does not introduce a new concept. The additional medications within the value sets allow for better compliance and the inclusion of more clinician types allows for assessment of a more complete patient population; however, they do not significantly change measure Q134 and allow for direct comparison of performance data from prior years. **Comment:** One commenter supported the revised measure descriptor for measure Q134. The commenter understood the numerator includes patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized tool AND if positive, a follow-up plan is documented on the date of the eligible encounter, the commenter requested that CMS consider screenings provided that are not necessarily associated with a face to face encounter. Allowing screenings to be considered by telephone, would allow for more opportunities in the numerator. **Response:** We thank the commenter for supporting the revision to measure Q134. We encourage the commenter to reach out to the measure steward and collaborate regarding further refinement of measure Q134 for proposal for future years. We proposed a substantive change to the description; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state: **The measure description is revised to read:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. This additional refinement ensures alignment in language across all collection types and does not affect the intent of the proposed substantive change. There were no additional refinements to substantive changes: **Updated denominator:** Added speech language pathology MIPS eligible clinician type. **For the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications:** Added physical therapy MIPS eligible clinician type. **Updated denominator exception:** Updated language to situations where the patient's cognitive capacity, functional capacity or motivation to improve may impact the accuracy of results of standardized depression assessment. **The numerator is revised to read:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **For the eCQM Specifications collection type:** Updated the “Depression medications – adolescent” and the “Additional evaluation for depression – adolescent” value sets to include additional medications. After consideration of the comments, we are finalizing the changes as indicated to measure Q134 for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.	

D.17. Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384/0384e
Quality #:	143
CMS eCQM ID:	CMS157v8
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated Guidance: For the eCQM Specifications collection type:** This measure is an episode-of-care measure; the level of analysis for this measure is every visit for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter where the patient and physician have a face-to-face interaction. Due to the nature of some applicable coding related to the radiation therapy (e.g., delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face encounter date. In this instance, for the reporting purposes of this measure, the billing date should be used to pull the appropriate patients into the initial population. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face encounter during the series of treatments. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy within 30 days prior to the encounter AND administered chemotherapy within 30 days after the date of the encounter.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the guidance within the eCQM Specifications collection type to address the limitations of the radiation treatment management code 77427 and to provide clarification about the variation in how this code is applied versus how the measure performance is assessed.
We received no comments on the substantive changes proposed for measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. Therefore, we are finalizing the changes to measure Q143 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.18. Oncology: Medical and Radiation - Plan of Care for Pain

Category	Description
NQF # / eCQM NQF #:	0383
Quality #:	144
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.
Substantive Change:	**Updated the description to read**: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain. **Updated the denominator to read:** All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having pain All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain **Updated the numerator to read:** Patient visits that included a documented plan of care to address pain
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revert this measure to the 2018 performance period measure specification. The 2019 measure narrows the patient population to those who report moderate to severe pain and require the plan of care before or on the data of the second visit with the clinician. The measure steward has submitted this version to NQF for re-endorsement where the measure steward received feedback to further test the updated analytics. As such, we agree with reverting to the NQF-endorsed measure. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

Comment: One commenter supported the substantive change proposed for measure Q144: Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain and reverting this measure to the 2018 performance period measure specifications. The commenter stated that the 2019 measure narrowed the patient population to those who report moderate to severe pain and requires the plan of care before or on the data of the second visit with the clinician. The measure steward has submitted this version to NQF for re-endorsement and received feedback to further test the updated analytics. The commenter also recommended that the measure title be changed to "Oncology: Medical and Radiation - Plan of Care for Pain," in order to align with the proposed reversion to 2018 specifications.

Response: We thank the commenter for supporting the revision to measure Q144. We agree that the title should align with the finalized revisions, and have reflected this update.

We proposed a substantive change to the denominator; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:
Updated the denominator to read:
All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain. This additional refinement does not affect the intent of the proposed substantive change.
We proposed to revert the measure to the 2018 MIPS version; however, during public comment it was noticed that the title was not updated to align with revisions being made to measure Q144. The title is being updated to state:
Oncology: Medical and Radiation - Plan of Care for Pain
These additional refinements ensure that the measure was reverted to the 2018 MIPS version of the specification and to be in alignment with the NQF-endorsed measure as proposed.

There were no additional refinements to substantive changes:
Updated the description to read: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.

All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain

Updated the numerator to read: Patient visits that included a documented plan of care to address pain

After consideration of the comments, we are finalizing the changes to measure Q144 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.

D.19. Rheumatoid Arthritis (RA): Tuberculosis Screening

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).
Substantive Change:	**Updated definition:** Biologic DMARD Therapy- Includes Abatacept (Orencia), Adalimumab (Humira), Adalimumab-adbm (Cyltezo), Adalimumab-atto (Amjevita), Anakinra (Kineret), Baricitinib (Olumiant), Certolizumab pegol (Cimzia), Etanercept (Enbrel), Etanercept-szzs (Erelzi), Golimumab (Simponi), Infliximab (Remicade), Infliximab-abda (Renflexis), Infliximab-dyyb (Inflectra), Infliximab-qbtx (Ixifi), Sarilumab (Kevzara), Tocilizumab (Actemra), Tofacitinib (Xeljanz).
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add Baricitinib (olumiant) and remove Rituximab (Rituxan) to the definition of "Biologic DMARD Therapy" as it was approved in 2018 by the FDA for the treatment of rheumatoid arthritis. We agree with the inclusion of Baricitinib in order to capture the relevant patient population. This revision allows eligible clinicians to achieve performance with use of a new pharmacological therapy to treat RA.
We received no comments on the substantive changes proposed for measure Q176: Rheumatoid Arthritis (RA): Tuberculosis Screening. Therefore, we are finalizing the changes to measure Q176 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.20. Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
NQF # / eCQM NQF #:	2523
Quality #:	177
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity at ≥50% of encounters for RA for each patient during the measurement year.
Substantive Change:	**Updated description:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year. **Updated definition:** Removed Patient Activity Scale (PAS) from definition of "Assessment of Disease Activity".
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward recently conducted an assessment of available RA disease activity tools and is updating the list of tools they will endorse. The Patient Activity Scale (PAS) will no longer be an ACR-preferred rheumatoid arthritis disease activity measurement tool and as such, we proposed to remove this scale as an acceptable assessment tool within this measure and update the description to align with this revision.
We received no comments on the substantive changes proposed for measure Q177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity. Therefore, we are finalizing the changes to measure Q177 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.21. Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	180
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months. **The numerator is revised to read:** Patients who have been assessed for glucocorticoid use and for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of a glucocorticoid management plan within 12 months.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that this measure be revised to expand the numerator population being assessed for improvement or no change in disease activity by dropping the prolonged doses of prednisone from ≥ 10 mg daily (or equivalent) to > 5 mg daily (or equivalent). The measure steward conducted literature review that found a nearly 2-fold greater serious infection at 5-10 mg of prednisone in RA. This change takes into consideration the dangers to patients associated with being on 5-10 mg doses of prednisone. We agree with the decision to drop the dosage of prednisone to > 5 mg daily (or equivalent) given it aligns more closely to dosing associated with patient risk and it is important to include these patients in the population being assessed for improvement or no change.
We received no comments on the substantive changes proposed for measure Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management. Therefore, we are finalizing the changes to measure Q180 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.22. Elder Maltreatment Screen and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	181
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.
Substantive Change:	**Updated denominator:** Added physical and occupational therapy, ophthalmology, audiology and speech language pathology MIPS eligible clinician types.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed, based upon requests from stakeholders, that coding be added to the denominator eligible encounters to include physical/occupational therapy, ophthalmology, audiology and speech language pathology MIPS eligible clinician types. This expansion of the numerator allows this measure to be used in an additional setting. We agree that this measure is clinically relevant for the physical therapy setting.
Comment: One commenter supported the addition of the physical therapy codes to measure Q181: Elder Maltreatment Screen and Follow-Up Plan. **Response:** We thank the commenter for supporting the revision to measure Q181. Also, note, we acknowledge eligible clinicians providing occupational therapy services were previously eligible to submit this measure and are not being newly added to measure Q182; however, the coding for occupational therapy has been expanded within the measure. After consideration of the comments, we are finalizing the changes to measure Q181 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.23. Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	2624
Quality #:	182
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.
Substantive Change:	**Updated denominator:** Added mental/behavioral health, audiology, and speech language pathology MIPS eligible clinicians.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed that the denominator be expanded to include coding for more MIPS eligible clinicians. We agree with the decision to expand the MIPS eligible clinician types as it is clinically relevant to this clinician type and allows for the removal of duplicative quality measures promoting functional assessment.

Comment: One commenter requested that CMS include RA diagnosis codes in measure Q182: Functional Outcome Assessment if measure Q178: Rheumatoid Arthritis (RA): Functional Status Assessment measure was finalized for removal from MIPS, which would allow rheumatologists to be compared to peers who report this measure.

Response: We thank the commenter for their comment. Measure Q182 only includes settings without any diagnosis coding within the denominator criteria as this is a broadly applicable measure. We encourage the commenter to reach out to the measure steward in order to collaborate on revisions for proposal in future years.

After consideration of the comments, we are finalizing the changes to measure Q182 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years, with the exception of the inclusion of mental/behavioral health MIPS eligible clinicians in the denominator. The measure steward would like to further discuss this expansion with their expert work group before including these codes to ensure they are appropriate for measure Q182.

D.24. Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
NQF # / eCQM NQF #:	0565 / 0565e
Quality #:	191
CMS eCQM ID:	CMS133v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.
Substantive Change:	**The measure description is revised to read:** Percentage of cataract surgeries for patients aged 18 and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery. **The initial population is revised to read: For the eCQM Specifications collection type:** All cataract surgeries for patients aged 18 years and older who did not meet any exclusion criteria. **The denominator is revised to read: For the MIPS CQMs Specifications collection type:** All cataract surgeries for patients aged 18 years and older who did not meet any exclusion criteria. **The denominator exclusion is revised to read:** Cataract surgeries in patients with significant ocular conditions impacting the visual outcome of surgery. **Update denominator exclusions:** Removed the following data elements/value sets: 'Chorioretinal Scars,' 'Moderate or Severe Impairment, Better Eye, Profound Impairment, Lesser Eye,' 'Other Corneal Deformities,' 'Other Disorders of Sclera,' 'Other Retinal Disorders,' and 'Profound Impairment, Both Eyes'. Add the following data elements/value sets: 'Cataract, Congenital,' 'Cataract, Mature or Hypermature,' 'Cataract, Posterior Polar,' 'Hypotony of Eye,' 'Macular Scar of Posterior Polar' (new value set), 'Morgagnian Cataract,' 'Posterior Lenticonus,' 'Retrolental Fibroplasias,' 'Traumatic Cataract,' and 'Vascular Disorders of Iris and Ciliary Body'. **The numerator is revised to read:** Cataract surgeries with best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following cataract surgery.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed that the measure language be updated to reflect that it is not a patient-based measure, but rather a measure that assesses cataract surgeries. The measure steward believes and we agree this update in language better aligns to the measure intent and implementation and also aligns with the current measure guidance. The measure steward convened an Eye Care technical expert panel (TEP) who also agreed that these language updates would provide more clarity around the intent, and be more explicit. The Eye Care TEP also reviewed and evaluated the denominator exclusions resulting in removal and addition of data elements/value sets outlined above.

Category	Description
	Comment: One commenter opposed the substantive change to measure Q191: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery (eCQM: CMS133v8). Within the context of this comment, the commenter opposed the removal of measure Q192: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (eCQM: CMS132v8), including to the changes to 2020 eCQM specifications for Q191 and Q192 (see response under Table C for further details on measure Q192). The commenter stated that for the past several years, the guidance language included in these measure specifications directly conflicted with the numerator and denominator specifications, which are used for calculation. The eligible population has been very clearly defined as "All patients aged 18 years and older who had cataract surgery and did not meet any exclusion criteria", and the numerator was also very clearly specified as "patients who had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following cataract surgery." The measure guidance language, however, said that every cataract surgery during the measurement period should be counted. This has been a flaw in the measure specification, and because both instructions cannot be true, the numerator and denominator language are what has been used for implementation over the past several years. For 2020, the measure owner, PCPI, changed the verbiage for these measures from "Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract…" to "Percentage of cataract surgeries for patients aged 18 years and older…". The commenter indicated this change is very concerning because it significantly increases reporting burden for ophthalmologists reporting the measure. The commenter stated that the guidance language that PCPI introduced into the specifications for the 2020 reporting year should be clarified to explain that measure evaluation should be at the per patient level. The commenter stated that the proposed change should not be finalized for the MIPS CQM versions of the measures and should be reversed for the eCQM versions of measures Q191 and Q192, which have already been published. **Response:** We thank the commenter for their comment; however, the language change aligns with the measure intent and implementation, which is episode-based and not patient-based per the measure steward. The measure steward convened an Eye Care technical expert panel (TEP) that agreed these changes would be more explicit regarding the measure intent. We believe an episode-based measure gives a more complete data set as the outcome for the operative eye from every cataract surgery should be analyzed for best-corrected visual acuity. We proposed a substantive change to the description; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state: **The measure description is revised to read:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery. This additional refinement aligns language throughout the specification and does not affect the intent of the proposed substantive change. Additionally, the denominator exclusion language revision will be finalized for the eCQM Specifications collection type only as the language within the MIPS CQMs Specifications collection type correctly reflects the intent of the denominator exclusion. There were no additional refinements to substantive changes: **The initial population is revised to read: For the eCQM Specifications collection type:** All cataract surgeries for patients aged 18 years and older who did not meet any exclusion criteria. **The denominator is revised to read: For the MIPS CQMs Specifications collection type:** All cataract surgeries for patients aged 18 years and older who did not meet any exclusion criteria. **The denominator exclusion is revised to read:** Cataract surgeries in patients with significant ocular conditions impacting the visual outcome of surgery. **Update denominator exclusions:** Removed the following data elements/value sets: 'Chorioretinal Scars,' 'Moderate or Severe Impairment, Better Eye, Profound Impairment, Lesser Eye,' 'Other Corneal Deformities,' 'Other Disorders of Sclera,' 'Other Retinal Disorders,' and 'Profound Impairment, Both Eyes'. Add the following data elements/value sets: 'Cataract, Congenital,' 'Cataract, Mature or Hypermature,' 'Cataract, Posterior Polar,' 'Hypotony of Eye,' 'Macular Scar of Posterior Polar' (new value set), 'Morgagnian Cataract,' 'Posterior Lenticonus,' 'Retrolental Fibroplasias,' 'Traumatic Cataract,' and 'Vascular Disorders of Iris and Ciliary Body'. **The numerator is revised to read:** Cataract surgeries with best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following cataract surgery After consideration of the comments, we are finalizing the changes as indicated to measure Q191 for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.

D.25. Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	0422
Quality #:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the knee impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the knee and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a knee impairment, who has had an interruption of a Treatment Episode for the same functional knee deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1009) identifying the close of a Treatment Episode for the same knee deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional knee deficit, progressing through treatment without interruption (for example a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a knee deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with knee impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. The numerator is revised to read: Patients who were presented with the Knee FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met.

Category	Description
	We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we proposed to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

We proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Documentation stating patient has a diagnosis of a degenerative neurological condition such as ALS, MS, or Parkinson's diagnosed at any time before or during the episode of care. This additional refinement does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
Updated numerator: Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the knee impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met.

Updated definitions: Removed:
(1) Admission (Option 1 & 2)
(2) Admission (Option 3 & 4)
(3) Discharge (Option 1 & 2)
(4) Discharge (Option 3 &4)
Added:
(1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the knee and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a knee impairment, who has had an interruption of a Treatment Episode for the same functional knee deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation.
(2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1009) identifying the close of a Treatment Episode for the same knee deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode.
Updated:
Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional knee deficit, progressing through treatment without interruption (for example a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a knee deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician.

Updated denominator: Consolidated all options into one denominator criteria.
The denominator is revised to read: All patients 14 years and older with knee impairments who have initiated a Treatment Episode.

Updated denominator exceptions: Added the following:
(1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown).
(2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery.
(3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only).

Moved from denominator exclusion to denominator exception
(1) Patient refused to participate.

The numerator is revised to read: Patients who were presented with the Knee FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

We received no comments on the substantive changes proposed for measure Q217: Functional Status Change for Patients with Knee Impairments. Therefore, we are finalizing the changes to measure Q217 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.

D.26. Functional Status Change for Patients with Hip Impairments

Category	Description
NQF # / eCQM NQF #:	0423
Quality #:	218
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the hip impairment successfully calculated and the score was less than zero (< 0)" will become Performance Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the hip and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a hip impairment, who has had an interruption of a Treatment Episode for the same functional hip deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1010) identifying the close of a Treatment Episode for the same hip deficit identified at Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional hip deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a hip deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with hip impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care no indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery.). (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read**: Patients who were presented with the Hip FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We proposed that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we proposed to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

We proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Documentation stating patient has a diagnosis of a degenerative neurological condition such as ALS, MS, or Parkinson's diagnosed at any time before or during the episode of care. This additional refinement does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
Updated numerator: Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the hip impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met.

Updated definitions: Removed:
(1) Admission (Option 1 & 2)
(2) Admission (Option 3 & 4)
(3) Discharge (Option 1 & 2)
(4) Discharge (Option 3 &4)
Added:
(1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the hip and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a hip impairment, who has had an interruption of a Treatment Episode for the same functional hip deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation.
(2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1010) identifying the close of a Treatment Episode for the same hip deficit identified at Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode.
Updated:
Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional hip deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a hip deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician.

Updated denominator: Consolidated all options into one denominator criteria.
The denominator is revised to read: All patients 14 years and older with hip impairments who have initiated a Treatment Episode.

Updated denominator exceptions: Added the following:
(1) Ongoing care no indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown).
(2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery.).
(3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only).

Moved from denominator exclusion to denominator exception
(1) Patient refused to participate.

The numerator is revised to read: Patients who were presented with the Hip FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

We received no comments on the substantive changes proposed for measure Q218: Functional Status Change for Patients with Hip Impairments. Therefore, we are finalizing the changes to measure Q218 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.

D.27. Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / ECQM NQF #:	0424
Quality #:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the lower leg, foot, or ankle impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the lower leg, foot or ankle and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a lower leg, foot or ankle impairment, who has had an interruption of a Treatment Episode for the same functional lower leg, foot or ankle deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1011) identifying the close of a Treatment Episode for the same lower leg, foot or ankle deficit identified at the Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional lower leg, foot or ankle deficit, progressing through treatment, without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a foot, ankle or lower leg deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with foot, ankle or lower leg impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care no indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read:** Patients who were presented with the Foot/Ankle FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes

Category	Description
Measure Type:	Patient Reported Outcome
Rationale:	We proposed that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we proposed to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

We proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Documentation stating patient has a diagnosis of a degenerative neurological condition such as ALS, MS, or Parkinson's diagnosed at any time before or during the episode of care. This additional refinement does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
Updated numerator: Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the lower leg, foot, or ankle impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met.

Updated definitions: Removed:
(1) Admission (Option 1 & 2)
(2) Admission (Option 3 & 4)
(3) Discharge (Option 1 & 2)
(4) Discharge (Option 3 &4)
Added:
(1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the lower leg, foot or ankle and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a lower leg, foot or ankle impairment, who has had an interruption of a Treatment Episode for the same functional lower leg, foot or ankle deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation.
(2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1011) identifying the close of a Treatment Episode for the same lower leg, foot or ankle deficit identified at the Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode.
Updated:
Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional lower leg, foot or ankle deficit, progressing through treatment, without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a foot, ankle or lower leg deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician.

Updated denominator: Consolidated all options into one denominator criteria.
The denominator is revised to read: All patients 14 years and older with foot, ankle or lower leg impairments who have initiated a Treatment Episode.

Updated denominator exceptions: Added the following:
(1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown).
(2) Ongoing care no indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery.
(3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only).

Moved from denominator exclusion to denominator exception
(1) Patient refused to participate.

The numerator is revised to read: Patients who were presented with the Foot/Ankle FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

We received no comments on the substantive changes proposed for measure Q219: Functional Status Change for Patients with Lower Leg, Foot, or Ankle Impairments. Therefore, we are finalizing the changes to measure Q219 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.

D.28. Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF # / ECQM NQF #:	0425
Quality #:	220
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the low back impairment successfully calculated and the score was less than zero (< 0)" will become Performance Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the low back and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a low back impairment, who has had an interruption of a Treatment Episode for the same functional low back deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1012) identifying the close of a Treatment Episode for the same low back deficit identified at Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a Discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional low back deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for a low back functional deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with a low back impairment who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. The numerator is revised to read: Patients who were presented with the Low Back FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We proposed that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we proposed to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

We proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Documentation stating patient has a diagnosis of a degenerative neurological condition such as ALS, MS, or Parkinson's diagnosed at any time before or during the episode of care. This additional refinement does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
Updated numerator: Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the low back impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met.

Updated definitions: Removed:
(1) Admission (Option 1 & 2)
(2) Admission (Option 3 & 4)
(3) Discharge (Option 1 & 2)
(4) Discharge (Option 3 &4)
Added:
(1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the low back and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a low back impairment, who has had an interruption of a Treatment Episode for the same functional low back deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation.
(2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1012) identifying the close of a Treatment Episode for the same low back deficit identified at Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a Discharge from the current Treatment Episode.
Updated:
Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional low back deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for a low back functional deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician.

Updated denominator: Consolidated all options into one denominator criteria.
The denominator is revised to read: All patients 14 years and older with a low back impairment who have initiated a Treatment Episode.

Updated denominator exceptions: Added the following:
(1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown).
(2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery.
(3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only).

Moved from denominator exclusion to denominator exception
(1) Patient refused to participate.

The numerator is revised to read: Patients who were presented with the Low Back FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

We received no comments on the substantive changes proposed for measure Q220: Functional Status Change for Patients with Low Back Impairments. Therefore, we are finalizing the changes to measure Q220 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.

D.29. Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF # / ECQM NQF #:	0426
Quality #:	221
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the shoulder impairment successfully calculated and the score was less than zero (< 0)" will become Performance Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the shoulder and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a shoulder impairment, who has had an interruption of a Treatment Episode for the same functional shoulder deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1013) identifying the close of a Treatment Episode for the same shoulder deficit identified at the Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional shoulder deficit, progressing through treatment, without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for a shoulder functional deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with shoulder impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read:** Patients who were presented with the Shoulder FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We proposed that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we proposed to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

We proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Documentation stating patient has a diagnosis of a degenerative neurological condition such as ALS, MS, or Parkinson's diagnosed at any time before or during the episode of care. This additional refinement does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
Updated numerator: Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the shoulder impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met.

Updated definitions: Removed:
(1) Admission (Option 1 & 2)
(2) Admission (Option 3 & 4)
(3) Discharge (Option 1 & 2)
(4) Discharge (Option 3 &4)
Added:
(1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the shoulder and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a shoulder impairment, who has had an interruption of a Treatment Episode for the same functional shoulder deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation.
(2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1013) identifying the close of a Treatment Episode for the same shoulder deficit identified at the Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode.
Updated:
Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional shoulder deficit, progressing through treatment, without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for a shoulder functional deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician.

Updated denominator: Consolidated all options into one denominator criteria.
The denominator is revised to read: All patients 14 years and older with shoulder impairments who have initiated a Treatment Episode.

Updated denominator exceptions: Added the following:
(1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown).
(2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery.
(3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only).

Moved from denominator exclusion to denominator exception
(1) Patient refused to participate.

The numerator is revised to read: Patients who were presented with the Shoulder FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

We received no comments on the substantive changes proposed for measure Q221: Functional Status Change for Patients with Shoulder Impairments. Therefore, we are finalizing the changes to measure Q221 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.

D.30. Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF # / ECQM NQF #:	0427
Quality #:	222
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the elbow, wrist, or hand impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the elbow, wrist, or hand and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with an elbow, wrist, or hand impairment, who has had an interruption of a Treatment Episode for the same functional knee deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1014) for identifying the close of a Treatment Episode for the same elbow, wrist or hand deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional elbow, wrist or hand deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for an elbow, wrist or hand deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with elbow, wrist or hand impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read:** Patients who were presented with the Elbow/Wrist/Hand FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes

Category	Description
Measure Type:	Patient Reported Outcome
Rationale:	We proposed the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it will create a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we proposed to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

We proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Documentation stating patient has a diagnosis of a degenerative neurological condition such as ALS, MS, or Parkinson's diagnosed at any time before or during the episode of care. This additional refinement does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
Updated numerator: Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the elbow, wrist, or hand impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met.

Updated definitions: Removed:
(1) Admission (Option 1 & 2)
(2) Admission (Option 3 & 4)
(3) Discharge (Option 1 & 2)
(4) Discharge (Option 3 &4)
Added:
(1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the elbow, wrist, or hand and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with an elbow, wrist, or hand impairment, who has had an interruption of a Treatment Episode for the same functional knee deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation.
(2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1014) for identifying the close of a Treatment Episode for the same elbow, wrist or hand deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode.
Updated:
Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional elbow, wrist or hand deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for an elbow, wrist or hand deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician.

Updated denominator: Consolidated all options into one denominator criteria.
The denominator is revised to read: All patients 14 years and older with elbow, wrist or hand impairments who have initiated a Treatment Episode.
Updated denominator exceptions: Added the following:
(1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown).
(2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery.
(3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only).

Moved from denominator exclusion to denominator exception
(1) Patient refused to participate.

The numerator is revised to read: Patients who were presented with the Elbow/Wrist/Hand FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

We received no comments on the substantive changes proposed for measure Q222: Functional Status Change for Patients with Elbow, Wrist, or Hand Impairments. Therefore, we are finalizing the changes to measure Q222 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.

D.31. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / ECQM NQF #:	0028 / 0028e
Quality #:	226
CMS eCQM ID:	CMS138v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. **Updated denominator: For the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types:** Added physical therapy MIPS eligible clinician type. **Updated Guidance: For the Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection types:** Added: (1) The denominator of population criteria 2 is a subset of the resulting numerator for population criteria 1, as population criteria 2 is limited to assessing if patients identified as tobacco users received an appropriate tobacco cessation intervention. For all patients, population criteria 1 and 3 are applicable, but population criteria 2 will only be applicable for those patients who are identified as tobacco users. Therefore, data for every patient that meets the initial population criteria will only be submitted for population 1 and 3, whereas data submitted for population 2 will be for a subset of patients who meet the initial population criteria, as the denominator has been further limited to those who were identified as tobacco users. (2) To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the 24-month period. If a patient has multiple tobacco use screenings during the 24-month period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements. **Updated instructions: For the MIPS CQM Specifications collection types:** This measure is to be submitted a minimum of once per performance period for patients seen during the performance period. This measure is intended to reflect the quality of services provided for preventive screening for tobacco use. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provided the measure-specific denominator coding. For this implementation of the measure, the 24 month look back period includes the program year and the year prior. For Quality Payment Program (QPP) 2020, the 24 month period would be from 1/1/2019-12/31/2020. **Updated guidance: For the CMS Web Interface Measure Specifications collection types:** • If there is more than 1 patient query regarding tobacco use, use the most recent query during the 24-month period to determine tobacco status. • "Within 24 months" is defined as the 24-month look-back from the measurement period end date (1/1/2019 - 12/31/2020). • Screening for tobacco use may be completed during a telehealth encounter. • Tobacco cessation intervention can be performed by another healthcare provider; therefore, the tobacco use screening and tobacco cessation intervention do not need to be performed by the same provider or clinician. • Screening for tobacco use and cessation intervention do not have to occur on the same encounter, but both must occur during the 24-month look-back period. • Screening for tobacco use and cessation intervention may be completed during a telehealth encounter. • Tobacco cessation intervention may be completed during a telehealth encounter.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process

Category	Description
Rationale:	We proposed that the measure description be revised to clarify the summarized intent for population criteria 2. Based upon requests from stakeholders, physical therapy evaluation codes was also proposed for addition in the denominator eligible encounters for the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection types to allow for this measure to be used in an additional setting. We agree that this preventive assessment is a clinically relevant measure for clinicians in the physical therapy setting. We proposed refinements to the guidance for the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications collection types in response to stakeholder feedback regarding the timing for which tobacco cessation intervention must occur. In response to our determination and stakeholder feedback for the CMS Web Interface Measure Specifications, Medicare Part B Claims Measure Specifications, and MIPS CQMs Specifications collection types, we proposed to allow a 24-month period to assess for tobacco cessation intervention. These refinements are in alignment with the clinical guidelines and will decrease burden for eligible clinicians performing tobacco screening and tobacco cessation intervention. The timing refinement as proposed would maintain the balance of clinical guideline and measure alignment, and support our effort to reduce burden for measure submission. Additionally, this timing refinement allows the clinician to create personalized, patient-centered care while still maintaining the clinical integrity of the measure and clinical guidelines. The CMS Web Interface Measure Specifications collection type was updated with additional guidance in order to add clarity regarding how this measure is implemented using that collection type. We also proposed updates to the instructions for MIPS CQMs Specifications collection types to further clarify the timing of the tobacco cessation intervention in alignment with the updated numerator guidance. We agree this proposal will maintain clinical intent, provide clarity, reduce clinician burden, and allow for personalized patient care. We also proposed updates to guidance for the Medicare Part B Claims Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications collection types based upon stakeholder feedback requesting clarification regarding interpretation of the three rates included in this measure.

Category	Description
Comment: Several commenters supported the substantive change for the Web Interface for measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention for the 2020 Performance Period as the change adds clarity to the measure. Another commenter supported the addition of the physical therapy codes to the measure. One commenter reviewed the proposed changes to the CMS Web Interface Measure Specifications collection type for measure Q226 and believed there are impacts to the benchmarks and a need to provide pay-for-reporting for 2019 and 2020 MIPS performance periods. One commenter indicated that CMS and the measure owner have been unable to provide sufficient clarity about this measure to make the results fair, accurate, or meaningful. There is no consistent guidance on what tobacco is. For some, it includes only cigarettes and cigars. For others, it includes snuff, snus, and other smokeless tobacco products. And, there has been a lack of clarity regard how a person must be referred following a positive initial screen. The commenter recommended that until there is a clearer understanding of PREV-10 requirements, that CMS make this pay-for-reporting measure for 2020 for MSSP and Next Generation ACOs. One commenter supported proposed revisions to measure Q226 that would add in telehealth encounters to be included as eligible encounters. One commenter recommended that physical therapists not be included in the denominator for ACO-17 (measure Q226), as this smoking cessation counseling is outside the scope of physical therapy. The commenter urged CMS to carefully study the impact of such changes on performance and benchmarks for this measure. Another commenter supported the proposed change to measures Q226 as it greatly reduce provider burden. **Response:** We thank the commenters for supporting the revision to measure Q226. Under MIPS, there is no pay-for-reporting option. In these instances, we exclude the measure from MIPS scoring for the CMS Web Interface Measure Specifications collection type in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement for the impacted performance period. For this substantive change, we disagree with the commenter that the measure should be excluded from MIPS scoring for the 2020 MIPS performance period as these changes align with the measure intent per feedback for the measure steward as the intent "of the measure is to screen patients for any and all types of tobacco use, as the guidelines that exist support intervention for any type of tobacco use, not just limited to smoking. That being said, measures are not guidelines and there is a decision that must be made by measure developers regarding how to construct a measure keeping in mind the evidence and ensuring that the resulting measure is feasible, useable, and positively impacts patient care. Therefore, for purposes of the measure, as long as a provider has documented status for any type of tobacco (that is., smokes or uses smokeless tobacco), that meets the first component of the numerator and contributes to the aim of improving care." Additionally, the guidance states "If a patient uses any type of tobacco (that is, smokes or uses smokeless tobacco), the expectation is that they should receive tobacco cessation intervention: either counseling and/or pharmacotherapy." The measure specification also gives a definition for what suffices as "tobacco cessation intervention" and the guidance includes clarity that the tobacco cessation intervention can be performed by another healthcare provider in order to promote a team-based approach to patient care. Additionally, we will continue to require this measure for groups, APM Entities, and virtual groups reporting through the CMS Web Interface Measure Specifications collection type. However, due to the mid-year change to the measure specification (as discussed in more detail under section III.E.1.b) for Q226 in program year 2019, we are redesignating the CMS Web Interface Measure Specifications collection type for measure Q226 as "pay-for-reporting" in the Shared Savings Program as provided in § 425.502(a)(5) and we will exclude the measure from MIPS scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement and the measure was reported through the CMS Web Interface Measure Specifications collection type. For further discussion on how this measure will be scored under the MIPS Program Quality Performance Category see section III.K.3.c.(1) of this final rule. For further discussion on how this measure will be scored under the Shared Savings Program see section III.E.1.b of this final rule. Regarding the commenter concerned with the CMS Web Interface Measure Specifications collection type and the eCQM Specifications collection type being out of alignment if this change is finalized, we believe this change brings these two collection types in alignment. After consideration of the comments, we are finalizing the changes to measure Q226 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years, except for the expansion of the denominator to include the physical therapy MIPS eligible clinician type for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. However, because we value stakeholder feedback the measure steward has agreed to collect expert work group feedback regarding the request to expand the denominator to include physical therapy MIPS eligible clinician type prior to implementation.	

D.32. Controlling High Blood Pressure

Category	Description
NQF # / ECQM NQF #:	0018 / N/A
Quality #:	236
CMS eCQM ID:	CMS165v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period. **Updated denominator: For the eCQM Specifications collection type:** Removed Blood Pressure Visit grouping value set and added in the individual value sets. **Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. (2) Patients 66 year of age and older with advanced illness and frailty. **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Updated: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. Added: (1) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (3) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator/guidance:** Updated to allow blood pressures taken by a clinician from remote monitoring devices in a medical setting or in an offsite setting (that is, patient's domicile) to count towards the measure with additional clarification regarding usable blood pressure readings: -Not requiring the numerator blood pressure reading to be during a visit or overlap with a diagnosis of hypertension. (Applicable to eCQM only). -If the day of the last blood pressure reading there are multiple blood pressure readings on that day, use the lowest systolic and diastolic on that day. -The blood pressure reading that is being used should not come from an ED or inpatient visit. -Do not include blood pressure readings reported by or taken by the patient.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome

Category	Description
Rationale:	We proposed for the eCQM specifications collection type: In order to increase transparency of which value set is being used for encounters, the "Blood Pressure Visit" grouping value set is being removed so that individual value sets will be used. We proposed to update the allowable denominator exclusions to include patients 66 years of age and older with advanced illness and frailty, patients with dementia taking the listed medications, and patients who are living in a long-term institutional setting, such as a nursing home, for more than 90 days during the measurement period. The measure steward believes and we agree it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might be harmful for patients to receive a particular service when they should prioritize other services. Additionally, we believe that some of the services in this measure are not appropriate for patients who are living in a long-term institutional setting for more than 90 days during the measurement period. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians. Additionally, we proposed the measure guidance be updated to align with the 2018 measure guideline updates making it so that a visit is no longer required for the numerator blood pressure reading with additional guidance that blood pressure should not be taken during major events as this can artificially elevate blood pressure. In alignment with this, blood pressure readings from an ED or inpatient visit should not be used as a numerator blood pressure reading. The guidance is also being updated to allow blood pressure readings taken by a clinician from remote monitoring devices in a medical setting or in an offsite setting (that is, patient's domicile) to be numerator compliant. Patient reported blood pressure readings cannot be used for numerator compliance.

Comment: One commenter opposed not implementing the exclusion for adults 80 and older with frailty for measure Q236: Controlling High Blood Pressure. This exclusion is critical for focusing the measures on the population most likely to benefit from the measured services. Without this exclusion, this measure will be out of alignment with what is required for reporting.

One commenter expressed concern with the proposal on measure Q236 to update the denominator exclusions to exclude those who are living in a long-term institution setting, such as a nursing home. Rather than excluding these patients, who could benefit from high quality care, the commenter believed it is critical to ensure these patients receive the care they need.

Response: We thank the commenter for their comment, however this revision was not proposed and would be considered substantive. We believe introducing this concept without collaboration and clarification with the measure steward may create implementation variability for eligible clinicians. Therefore, we would encourage the commenter to work with the measure steward to incorporate this revision for future years. We thank the commenter for their comment expressing concern over the proposed changes to the denominator exclusions. The denominator exclusion for patients living long term in an institution is not new to this measure, but is being updated to require the patient to have spent more than 90 days within an institution, therefore, no longer excluding all patients who have lived in an institute during the measurement period. We disagree with the commenter that the measure should be made pay-for-reporting for the 2019 MIPS performance period as these revisions will be implemented for the 2020 MIPS performance period and do not affect the 2019 MIPS performance period. Additionally, we do not believe that the revisions necessitate an updated benchmark for the MIPS 2020 performance period as the updated denominator exclusions do not significantly change the patient population, but work to create a more relevant patient population for the quality action, which remains unchanged. We do not believe the revisions to the numerator/guidance are significant and will allow for direct comparison of performance data from prior years.

Comment: One commenter supported the denominator exclusions added for frailty for ACO-28 (measure Q236): Hypertension, Controlling High Blood Pressure. The commenter also requested that the age restriction is removed from these exclusions, as many of these interventions are not clinically appropriate in those with frailty and limited life expectancy due to advanced illness, regardless of age. The commenter recommended the following exclusion: Remove age restriction (below 65 years of age) for exclusion in a Long-Term Care Setting.

Response: We thank the commenter for supporting the revision to measure Q236. We encourage the commenter to reach out to the measure steward and collaborate regarding further refinement of the denominator exclusions.

Comment: One commenter reviewed the proposed changes to the CMS Web Interface Measures Specification type for measure Q236 and believed there are impacts to the benchmarks and a need to provide pay-for-reporting for the 2019 and 2020 MIPS performance periods.

Response: We thank the commenter for their comment. Under MIPS, there is no pay-for-reporting option. In these instances, we exclude the measure from MIPS scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement for the impacted performance period. For this substantive change, we disagree with the commenter that the measure should be excluded from MIPS scoring for the 2019 MIPS performance period as these revisions will be implemented for the 2020 MIPS performance period and do not affect the 2019 MIPS performance period. Additionally, we do not believe that the revisions necessitate an updated benchmark for the MIPS 2020 performance period as the updated denominator exclusions do not significantly change the patient population, but work to create a more relevant patient population for the quality action, which remains unchanged. We do not believe the revisions to the numerator/guidance are significant and will allow for direct comparison of performance data from prior years.

For the eCQM specifications collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
(1) Exclude patients 66 and older who are living long term in an institution for more than 90 days during the measurement period.
(2) Exclude patients 66 and older with advanced illness and frailty because it is unlikely that patients will benefit from the services being measured.
This additional refinement does not affect the intent of the proposed substantive change.

For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs collection type, we proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type: Added the following:
(2) Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 days during the measurement period
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified and to decrease clinician burden by outlining the coding for the denominator exclusion for measure Q001 and does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type: Added the following;
(2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period.
(3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period.
(4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine
Miscellaneous central nervous system agents: Memantine

Category	Description
The measure description is revised to read: Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period. **Updated denominator: For the eCQM Specifications collection type:** Removed Blood Pressure Visit grouping value set and added in the individual value sets. **Updated numerator/guidance:** Updated to allow blood pressures taken by a clinician from remote monitoring devices in a medical setting or in an offsite setting (that is, patient's domicile) to count towards the measure with additional clarification regarding usable blood pressure readings: -Not requiring the numerator blood pressure reading to be during a visit or overlap with a diagnosis of hypertension. (Applicable to eCQM only). -If the day of the last blood pressure reading there are multiple blood pressure readings on that day, use the lowest systolic and diastolic on that day. -The blood pressure reading that is being used should not come from an ED or inpatient visit. -Do not include blood pressure readings reported by or taken by the patient. After consideration of the comments, we are finalizing the changes as indicated to measure Q236 for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.	

D.33. Use of High-Risk Medications in the Elderly

Category	Description
NQF # / ECQM NQF #:	0022 / N/A
Quality #:	238
CMS eCQM ID:	CMS156v8
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.
Substantive Change:	**Updated numerator statement for submission criteria 2:** Percentage of patients who were ordered at least two of the same high-risk medications on different days. **Updated guidance:** Added 'on different days' to align with update to numerator submission criteria 2.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The numerator statement for submission criteria 2 was proposed to be updated to clarify that the assessment is looking for high-risk medications that are prescribed on different days, which is in alignment with the intent of the assessment being captured. This update is also reflected in the guidance.
We proposed a substantive change to the numerator statement for submission criteria 2; however; during the quality measure annual revision process with the measure steward, there was additional refinement. Therefore, we are finalizing the substantive change to state: **Updated numerator statement for submission criteria 2:** Patients with at least two orders for the same high-risk medication on different days during the measurement period. This additional refinement does not affect the intent of the proposed substantive change. This additional refinement was to ensure clarity in language so that the clinically appropriate quality action is identified for measure Q238 and does not affect the intent of the proposed substantive change. We received no comments on the substantive changes proposed for measure Q238: Use of High-Risk Medications in the Elderly. Therefore, we are finalizing the changes to measure Q238 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.	

D.34. Childhood Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	240
CMS eCQM ID:	CMS117v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday
Substantive Change:	**The measure description is revised to read:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. **Updated numerator:** Added value set for Hepatitis B carriers to allow Hepatitis B carriers to meet this part of the numerator. **Updated definition:** Removed 'Three HiB Vaccinations' and added new definition statements 'HiB 3 Dose Immunizations or Procedures,' 'HiB 4 Dose Immunizations or Procedures,' 'HiB 3 or 4 Dose Immunizations,' 'All HiB Vaccinations,' and 'Has Appropriate Number of HiB Immunizations.' Revised logic to include the correct number of HiB doses depending on the manufacturer of the vaccine given to align with current guidelines. Updated the logic for the HiB vaccine to require the correct amount of doses depending on the manufacturer of the vaccine given. Create a 3 dose and a 4 dose HiB vaccine.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the numerator be updated to include a value set for Hepatitis B carriers in order to allow this patient population to meet Hep B vaccine numerator compliance piece. We agree that this would suffice for the "had documented history of the illness" piece of numerator compliance. Additionally, we proposed that the measure logic be updated for the HiB vaccine to ensure the correct dosing is administered as instructed by the drug manufacturer's instructions and alignment with the current guidelines. The description is also being updated to align with this. We agree the logic should match the dosing of the vaccine given to ensure that the patient is receiving the correct and full dosage.
We received no comments on the substantive changes proposed for measure Q240: Childhood Immunization Status. Therefore, we are finalizing the changes to measure Q240 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.35. Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Category	Description
NQF # / eCQM NQF #:	0643
Quality #:	243
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.
Substantive Change:	**Updated denominator exceptions:** Added (1) Documentation of patient reason(s) for not referring to an outpatient CR program (for example, no traditional CR program available to the patient, within 60 min [travel time] from the patient's home, patient does not have access to an alternative model of CR delivery that meets all criteria for a CR program, patient refused or other patient reasons).
Steward:	American Heart Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed a new denominator exception be added to allow for documentation of patient reason(s) for not having a CR referral. The measure stewards believes denominator exceptions are used in select cases to allow for a fairer measurement of quality for those providers with higher risk populations. Exceptions are also used to defer to the clinical judgment of the provider. A MIPS eligible clinician who recommends CR referral to an eligible patient whom then refuses at the time of referral for one or more reasons (for example, lack of transportation, patient preference), will now be able to exclude this patient from the numerator population. In such a case, the MIPS eligible clinician will not be penalized based upon patient reason(s) for not having a CR referral. If the patient has told the physician that he/she does not wish to enroll in a CR program, the MIPS eligible clinician can document in the medical record that he/she has recommended referral but that the patient has refused CR. The measure steward believes this is important because, in this scenario, the MIPS eligible clinician should not be penalized for the lack of a completed CR program referral as long as the CR referral recommendation and the patient refusal are documented. By adding this exception, reasons for patient non-compliance can be better tracked to correspond with implementing practices that may improve compliance and thereby overall clinical care.

We proposed a substantive change to add a denominator exception; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:

Updated denominator exceptions: Documentation of patient reason(s) for not referring to an outpatient CR program. This additional refinement was to simply the concept in order to allow flexibility in application of the denominator exception identified for measure Q243 and does not affect the intent of the proposed substantive change.

We received no comments on the substantive changes proposed for measure Q243: Cardiac Rehabilitation Referral from an Outpatient Setting. Therefore, we are finalizing the changes to measure Q243 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.

D.36. Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	268
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.
Substantive Change:	**The measure description is revised to read:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy. **Updated denominator:** All females aged 12 years and older with a diagnosis of epilepsy. **Updated numerator:** Female patients or caregivers counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy **Updated denominator exceptions:** Removed (1) Documentation of medical reason(s) why counseling was not performed for women of childbearing potential with epilepsy (4340F with 1P) **Updated definition of "Counseling" -** Counseling must include a discussion of at least two of the following three counseling topics: • Need for folic acid supplementation, • Drug to drug interactions with contraception medication, • Potential anti-seizure medications effect(s) on fetal/child development and/or pregnancy.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator be expanded to include all females aged 12 years and older and that the denominator exception of "Documentation of medical reason(s) why counseling was not performed for women of childbearing potential with epilepsy" be removed as there is no longer an exception for patients with a diagnosis of neurodevelopmental disorder, encephalopathy, hydrocephalus, brain injury, cerebral palsy, severe cognitive impairment, or severe intellectual disability. The description is being updated to reflect the changes made to the denominator. The numerator action was updated to require counseling for both contraception and pregnancy in relation to epilepsy and how its treatment may affect. We agree with this requirement as both clinical aspects are important to the patient. The measure steward has requested, and we agree with, the denominator expansion and the removal of the denominator exception as they believe all women diagnosed with epilepsy at risk for pregnancy and/or pregnancy complications should be counseled.

We proposed a substantive change to the denominator; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:

Updated denominator: All females of childbearing potential (12 years and older) with a diagnosis of epilepsy. This additional refinement does not affect the intent of the proposed substantive change.
This additional refinement was to ensure clarity in language so that the clinically appropriate patient population is identified for measure Q268 and does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
The measure description is revised to read: Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.

Updated numerator: Female patients or caregivers counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy

Updated denominator exceptions: Removed
(1) Documentation of medical reason(s) why counseling was not performed for women of childbearing potential with epilepsy (4340F with 1P)

Updated definition of "Counseling" - Counseling must include a discussion of at least two of the following three counseling topics:
- Need for folic acid supplementation,
- Drug to drug interactions with contraception medication,
- Potential anti-seizure medications effect(s) on fetal/child development and/or pregnancy.

We received no comments on the substantive changes proposed for measure Q268: Counseling for Women of Childbearing Potential with Epilepsy. Therefore, we are finalizing the changes to measure Q268 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.

D.37. Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	283
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.
Substantive Change:	**Update denominator:** Added physical therapy MIPS eligible clinician type.
Steward:	American Psychiatric Association and American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator coding be expanded to include physical therapy as a denominator eligible encounter. We agree with the decision to expand this measure to physical therapy MIPS eligible clinicians as it is clinically relevant to this clinician type.
We received no comments on the substantive changes proposed for measure Q283: Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management. Therefore, we are finalizing the changes to measure Q283 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.38. Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	286
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.
Substantive Change:	**Updated denominator:** Added physical therapy MIPS eligible clinician type.
Steward:	American Psychiatric Association and American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed that the denominator coding be expanded to include physical therapy as a denominator eligible encounter. We agree with the decision to expand this measure to physical therapy MIPS eligible clinicians as it is clinically relevant to this clinician type.
We received no comments on the substantive changes proposed for measure Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia. Therefore, we are finalizing the changes to measure Q286 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.39. Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	290
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.
Substantive Change:	**Updated numerator options:** Performance Met: Psychosis, depression, anxiety, apathy, AND impulse control disorder assessed Performance Not Met: Psychosis, depression, anxiety, apathy, AND impulse control disorder not assessed
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the numerator options to better align with the intent of the measure, which requires assessment of five individual components of psychiatric symptoms. We agree with the measure steward that this update to the numerator options aligns with the intent of the measure.
We received no comments on the substantive changes proposed for measure Q290: Psychiatric Symptoms Assessment for Patient's with Parkinson's Disease. Therefore, we are finalizing the changes to measure Q290 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.40. Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	305
CMS eCQM ID:	CMS137v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. b. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention. **Updated initial population:** Changed intake period for the initial population to January 1 to November 14. Added telehealth services to initial population encounter value sets. **Updated numerator:** Added telehealth services to the numerator encounter value sets. Added Opiate Antagonists for numerator compliance **Numerator 1 is revised to read:** Initiation of treatment includes either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. **Numerator 2 is revised to read:** Engagement in ongoing treatment includes two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention (that is, engagement for these members cannot be satisfied with medication treatment alone).
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed that the initial population and numerator value sets be updated to include telehealth services. We agree with including telehealth services as they are appropriate for this measure and patients using these services should be included in the initial population as well as be considered for numerator compliance. Both numerators are being updated to add pharmacotherapy as a numerator compliant clinical quality action. Numerator 2 is also being updated to reflect the change in the time period for follow-up, which is increasing to 34 days from 30 days and to align with pharmacotherapy addition; patients who initiated treatment with a medication need two or more engagement events where only one can be a medication treatment event.
Comment: One commenter supported proposed revisions to measure Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment that would add in telehealth encounters to be included as eligible encounters. **Response:** We thank the commenter for supporting the revision to measure Q305. After consideration of the comments, we are finalizing the changes to measure Q305 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.41. Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	317
CMS eCQM ID:	CMS22v8
National Quality Strategy Domain:	Community /Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.
Substantive Change:	**Updated numerator: For the eCQM Specifications collection type:** Updated logic to allow for the documentation of a reason (finding of elevated blood pressure or hypertension) for scheduling a follow up visit and added value set "Finding of Elevated Blood Pressure or Hypertension". Added Potassium and Sodium codes to the Dietary Recommendation value set. **Updated numerator definition:** Added potassium and sodium for dietary/lifestyle recommendations.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the logic to allow for the documentation of a reason (finding of elevated blood pressure or hypertension) for scheduling a follow up visit which improves alignment with measure intent. This logic change will include the addition of a new values set "Finding of Elevated Blood Pressure or Hypertension" strengthening alignment with measure intent. We also proposed to add clinically relevant potassium and sodium codes to expand documentation options that align with the measure intent. This will also be reflected in the numerator definition.
Comment: One commenter supported the proposed changes to measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Document to update the logic to allow for the documentation of a reason for scheduling a follow-up visit. **Response:** We thank the commenter for supporting the revision to measure Q317. After consideration of the comments, we are finalizing the changes to measure Q317 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years except for the updated numerator definition. This update will be made to the logic of the eCQM Specifications collection type through updates within the Dietary Recommendation value set. The definitions as indicated in the 2020 MIPS specification remain appropriate for purposes of implementation.	

D.42. Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525
Quality #:	326
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Updated denominator:** Removed emergency medicine setting.
Steward:	American College of Cardiology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed and agree with the measure steward's request to remove the emergency department setting. Chronic anticoagulation therapy would be managed by a clinician providing continuous medical care which would not be applicable to the emergency medicine specialty.
We received no comments on the substantive changes proposed for measure Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy. Therefore, we are finalizing the changes to measure Q326 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.43. Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	332
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
Substantive Change:	**Updated denominator:** Changed requirements for denominator eligibility Patients aged ≥ 18 years on date of encounter AND **Diagnosis for bacterial and infectious agent** **OR** **Sinusitis caused by, or presumed to be caused by, bacterial infection** AND Patient encounter WITHOUT Telehealth Modifier AND Antibiotic regiment prescribed
Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed the measure no longer requires a diagnosis for bacterial and infectious agent to be denominator eligible as long as the sinusitis is caused by, or presumed to be caused by, bacterial infection. We agree that this change will not change the intent of the measure, but could lessen the burden to MIPS eligible clinicians by removing the requirement for a diagnosis.

Comment: One commenter responded to the substantive change proposed for measure Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) to make the bacterial/infectious agent codes optional. In 2019, these codes are required.

The commenter requested that the substantive change proposed for 2020 be made retroactively to the 2019 measure. The definition of Acute Bacterial Rhinosinusitis (ABRS) in the measure is that it is caused by, or presumed to be caused by, bacterial infection. Providers can diagnosis ABRS based on patient symptomology, thereby presuming it to be caused by a bacterial infection. The provider is prescribing an antibiotic based on that presumption. No culture is necessary. Additionally, requiring the culture results in undue and unnecessary costs for the patient. The commenter indicated the ICD10 codes included in the measure specifications allow for an unspecified diagnosis: J01.00 = acute maxillary sinusitis unspecified; J01.20 = acute ethmoidal sinusitis unspecified. If no culture is done but the provider diagnosis ABRS based on its definition and codes the visit using one of the "unspecified" ICD10 codes, the measure is met, or at least the intent of the measure. The commenter also specified that the measure steward intended the bacterial/infectious agent code to be optional; not required.

Response: We thank the commenter for supporting the revision to measure Q332. As this revision was proposed for the 2020 Performance Period only, it cannot be made retroactively to the 2019 measure specification.

After consideration of the comments, we are finalizing the "Sinusitis caused by, or presumed to be caused by, bacterial infections" denominator criteria be moved to an "OR" statement with "Diagnosis for bacterial and infectious agent" to measure Q332 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.

We are not finalizing the removal of the denominator criteria "Diagnosis for acute sinusitis" as this is necessary for determining the correct eligible patient population. The finalized denominator criteria will be as follows:

Patients aged ≥ 18 years on date of encounter
AND
Diagnosis for acute sinusitis
AND
Diagnosis for bacterial and infectious agents
OR
Sinusitis caused by, or presumed to be caused by, bacterial infection
AND
Patient encounter
WITHOUT
Telehealth Modifier
AND
Antibiotic regiment prescribed

D.44. Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	335
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication.
Substantive Change:	**The measure title is revised from Elective Delivery or Early Induction Without Medical Indication ≥ 37 and < 39 Weeks (Overuse) to read:** Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse). **The measure description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication. **Updated denominator:** Changed to include all deliveries at < 39 weeks of gestation. **Updated numerator:** Numerator options will be updated to reflect the measure now including all deliveries at < 39 weeks gestation.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed the measure population be expanded to include all deliveries at < 39 weeks of gestation. We agree with this change as delivery prior to 39 weeks of gestation increases risk to both the mother and baby. Induction prior to 39 weeks of gestation should only be performed when clinically indicated. It is important to have a complete population to ensure that all instances of early induction are being captured and assessed for proper clinical action.
We received no comments on the substantive changes proposed for measure Q335: Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse). Therefore, we are finalizing the changes to measure Q335 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.45. Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	336
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, and family and contraceptive planning.
Substantive Change:	**Updated description to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth and who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update. **Updated numerator:** Added clinical actions necessary for numerator compliance (1) Tobacco use screening and cessation education (2) Healthy lifestyle behavioral advice to bring the BMI within healthy limits (3) Immunization review and education
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	Three more components have been added to the list of clinical actions needed at a post-partum visit in order to be numerator compliant. The measure steward convened an expert work group (EWG) who, upon literature review, recommended adding these three clinical activities. The description was updated to align with the additional clinical actions. We agree and proposed that that these clinical actions should be included in a post-partum visit as they will positively impact patient health and are clinically valuable in supporting post-partum patients.

We proposed a substantive change to the numerator; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the numerator substantive change to state:
Updated numerator: Added clinical actions necessary for numerator compliance

Updated numerator:
(1) Tobacco use screening and cessation education
(2) Healthy lifestyle behavioral advice
(3) Immunization review and update
This additional refinement was to ensure clarity in language so that the intent of the measure is appropriately captured for measure Q336 and does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
Updated description to read: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth and who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.

For clarity of numerator compliance, additional definitions were provided within the Definition Section of the specification for each of the added numerator components.

We received no comments on the substantive changes proposed for measure Q336: Maternity Care: Postpartum Follow-Up and Care Coordination. Therefore, we are finalizing the changes to measure Q336 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.

D.46. Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	337
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.
Substantive Change:	**The description is revised to read:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test. **The numerator is revised to read:** Patients who have a documented negative TB screening or have documentation of the management of a positive TB screening test with no evidence of active tuberculosis, confirmed through use of radiographic imaging (that is, chest x-ray, CT) prior to treatment with a biologic immune response modifier.
Steward:	American Academy of Dermatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	Newly published psoriasis clinical guidelines recommend that tuberculosis (TB) screening tests be completed prior to treatment. Numerator compliance for this measure will now have a timing component associated with the TB screening tests and imaging as they need to be completed prior to treatment with a biologic immune response modifier. We agree and proposed this change as it follows the current clinical guidelines.
Comment: One commenter appreciated the substantive change to measure Q337: Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on A Biological Immune Response Modifier. **Response:** We thank the commenter for supporting the revision to measure Q337. After consideration of the comments, we are finalizing the changes to measure Q337 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.47. Pain Brought Under Control Within 48 Hours

Category	Description
NQF # / eCQM NQF #:	0209
Quality #:	342
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.
Substantive Change:	**Updated denominator:** Added the outpatient setting.
Steward:	National Hospice and Palliative Care Organization
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed that the denominator coding be expanded to include the outpatient setting as an applicable setting. We received prior stakeholder feedback with this request and agree with the decision to expand this measure to the outpatient MIPS eligible clinicians as it is clinically relevant to this setting.
We received no comments on the substantive changes proposed for measure Q342: Pain Brought Under Control Within 48 Hours. Therefore, we are finalizing the changes to measure Q342 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.48. Implantable Cardioverter-Defibrillator (ICD) Complications Rate

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	348
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.
Substantive Change:	**The measure title is revised from HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate to read:** Implantable Cardioverter-Defibrillator (ICD) Complications Rate.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the title to align with the measure steward changing from The Heart Rhythm Society to American College of Cardiology Foundation.
We received no comments on the substantive changes proposed for measure Q348: Implantable Cardioverter-Defibrillator (ICD) Complications Rate. Therefore, we are finalizing the changes to measure Q348 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.49. Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality #:	370
CMS eCQM ID:	CMS159v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**Updated denominator:** Allow PHQ-9/PHQ9M to be administered during the index encounter or up to 7 days prior to encounter.
Steward:	Minnesota Community Measurement
High Priority Measure:	No
Measure Type:	Outcome
Rationale:	The measure steward believes that allowing flexibility for the timeframe in which a PHQ-9/PHQ-9M can be obtained will accommodate pre-visit planning or distribution of a PHQ-9/PHQ-9M tool prior to the encounter (office visit, psychiatry or psychotherapy visit, telephone or online encounter). The intent of this change includes the following principles: (1) The patient must have the corresponding diagnosis at the time of the index encounter. (2) The patient must have completed the PHQ-9/PHQ-9M and have a score greater than 9. (3) That same PHQ-9/PHQ-9M is directly tied to and used during the index encounter. We agree and proposed this change as it will allow for pre-visit planning and administration of the tool while also accounting for clinical workflow. Additionally, this revision may lessen the burden of completing the PHQ-9/PHQ-9M tool during the health visit.

Comment: One commenter reviewed the proposed changes to the CMS Web Interface Measure Specification collection type for measure Q370: Depression Remission at Twelve Months and questioned whether the changes impact the benchmarks, but urged CMS to explore and consider whether the measure warrants pay-for-reporting for the 2019 and 2020 MIPS performance period. One commenter supported the update to the denominator to allow PHQ-9/PHQ9M to be administered during the index encounter or up to 7 days prior to encounter for measure Q370.

Response: We thank the commenter for their comment. Under MIPS, there is no pay-for-reporting option. In these instances, we exclude the measure from MIPS scoring for the CMS Web Interface Measures Specification collection type in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement for the impacted performance period. For this substantive change, we disagree with the commenter that the measure should be excluded from MIPS scoring for the 2019 MIPS performance period as these revisions will be implemented for the 2020 MIPS performance period and do not affect the 2019 MIPS performance period. Additionally, we do not believe that the revisions necessitate an updated benchmark for the MIPS 2020 performance period as the update to allow the screening to occur up to 7 days prior to the encounter better aligns with clinical practices and provides a better opportunity for compliance, however, the quality action being assessed has not changed. We thank the commenter for supporting the revision to measure Q370.

After consideration of the comments, we are finalizing the changes to measure Q370 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.

D.50. Functional Status Assessments for Congestive Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	377
CMS eCQM ID:	CMS90v9
National Quality Strategy Domain:	Person and Caregiver- Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.
Substantive Change:	**Updated numerator:** Added the Minnesota Living with Heart Failure Questionnaire (MLHQF) tool and the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) tool to the list of acceptable FSAs.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The Minnesota Living with Heart Failure Questionnaire (MLHQF) tool and the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) tool were proposed to be added to the list of numerator compliant tools that may be used to complete the measure's clinical action. The MLHQF tool has previously been approved by the measure steward's expert work group for inclusion in this measure and the KCCQ-12 tool is being included based upon expert feedback and stakeholder requests, as the measure already contains the KCCQ tool. We agree and proposed that both of these tools are relevant and appropriate for inclusion in this measure and, potentially, will capture an increased number of instances that meet numerator requirements.
We received no comments on the substantive changes proposed for measure Q377: Functional Status Assessments for Congestive Heart Failure. Therefore, we are finalizing the changes to measure Q377 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.51. Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	378
CMS eCQM ID:	CMS75v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period.
Substantive Change:	**The numerator is revised to read:** Children who had cavities or decayed teeth overlapping the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise the numerator statement to include a timing component for better alignment with numerator logic.
We received no comments on the substantive changes proposed for measure Q378: Children Who Have Dental Decay or Cavities. Therefore, we are finalizing the changes to measure Q378 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.52. Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	379
CMS eCQM ID:	CMS74v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.
Substantive Change:	**The numerator is revised to read:** Children who receive a fluoride varnish application during the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the numerator header to align with the numerator logic.
We received no comments on the substantive changes proposed for measure Q379: Primary Caries Prevention as Offered by Primary Care Providers, including Dentists. Therefore, we are finalizing the changes to measure Q379 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.53. Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	1365e
Quality #:	382
CMS eCQM ID:	CMS177v8
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.
Substantive Change:	**Updated numerator:** Added telehealth data element to "Major Depressive Disorder Encounter" definition using "Telehealth Services" value set (OID: 2.16.840.1.113883.3.464.1003.101.12.1031). **Updated guidance:** A suicide risk assessment should be performed at every visit for major depressive disorder during the measurement period. This measure is an episode-of-care measure; the level of analysis for this measure is every visit for major depressive disorder during the measurement period. For example, at every visit for MDD, the patient should have a suicide risk assessment. Use of a standardized tool(s) or instrument(s) to assess suicide risk will meet numerator performance, so long as the minimum criteria noted above is evaluated. Standardized tools can be mapped to the concept "Intervention, Performed": "Suicide risk assessment (procedure)" included in the numerator logic below, as no individual suicide risk assessment tool or instrument would satisfy the requirements alone. **Updated numerator definition:** The specific type and magnitude of the suicide risk assessment is intended to be at the discretion of the individual clinician and should be specific to the needs of the patient. At a minimum, suicide risk assessment should evaluate: (1) Risk (for example, age, sex, stressors, comorbid conditions, hopelessness, impulsivity) and protective factors (for example, religious belief, concern not to hurt family) that may influence the desire to attempt suicide. (2) Current severity of suicidality. (3) Most severe point of suicidality in episode and lifetime. Low burden tools to track suicidal ideation and behavior such as the Columbia-Suicidal Severity Rating Scale can also be used. Because no validated assessment tool or instrument fully meets the aforementioned requirements for the suicide risk assessment, individual tools or instruments have not been explicitly included in coding.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The measure steward's Technical Expert Panel (TEP) recommended adding telehealth services to the numerator eligible encounters. We agree and proposed that performing suicide risk assessments is a clinically relevant action that should be completed by MIPS eligible clinicians providing telehealth services for patients diagnosed with major depressive disorder. It is important for patient safety that this clinical action is being performed on all patients with this diagnosis regardless of setting. The guidance and numerator definition are being updated per TEP recommendations to clarify that while sample assessments are listed, they are not reflected in the coding of this measure because the assessments do not meet all of the requirements for the suicide risk assessment.

Comment: One commenter supported proposed revisions to measure Q382: Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment that would add in telehealth encounters to be included as eligible encounters.

Response: We thank the commenter for supporting the revision to measure Q382.

After consideration of the comments, we are finalizing the changes to measure Q382 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.

D.54. Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	385
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.
Substantive Change:	**Updated denominator exclusion:** Added an exclusion to remove patients with a pre-operative visual acuity of better than 20/40.
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise this measure to include a denominator exclusion to account for patients with a pre-operative visual acuity better than 20/40, as these patients would not be expected to show an improvement in visual acuity following surgical intervention. We believe these patients should be excluded based upon expected visual acuity outcomes. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.
Comment: One commenter supported the substantive change to add the exclusion to measure Q385, Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery, for patients with a pre-operative visual acuity of better than 20/40. This change was suggested by the commenter because, for these patients with good preoperative visual acuity, a successful retinal detachment repair will maintain this, and so thus, there could not be a measurable improvement in visual acuity. Therefore, it is appropriate to exclude these patients from the measure. **Response:** We thank the commenter for supporting the revision to measure Q385. After consideration of the comments, we are finalizing the changes to measure Q385 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.55. Follow-up After Hospitalization for Mental Illness (FUH)

Category	Description
NQF # / eCQM NQF #:	0576
Quality #:	391
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication/Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Substantive Change:	**Updated denominator:** Added self-harm as a denominator eligible diagnosis. **The measure description is revised to read:** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed the denominator be expanded to include patients diagnosed with self-harm. We agree that this patient population is relevant to this measure and follow-up after hospitalization for patients with a self-harm diagnosis is directly applicable to patient safety.
We received no comments on the substantive changes proposed for measure Q391: Follow-Up After Hospitalization for Mental Illness (FUH). Therefore, we are finalizing the changes to measure Q391 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.56. Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation

Category	Description
NQF # / eCQM NQF #:	2474
Quality #:	392
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older
Substantive Change:	**The measure title is revised from HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation to read:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the title to align with the measure steward changing from The Heart Rhythm Society to American College of Cardiology Foundation.
We received no comments on the substantive changes proposed for measure Q392: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation. Therefore, we are finalizing the changes to measure Q392 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.57. Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	393
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Infection rate following CIED device implantation, replacement, or revision.
Substantive Change:	**The measure title is revised from HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision to read:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the title to align with the measure steward changing from The Heart Rhythm Society to American College of Cardiology Foundation.
We received no comments on the substantive changes proposed for measure Q393: Infection within 180 Days of Cardiac Electronic Device (CIED) Implantation, Replacement, or Revision. Therefore, we are finalizing the changes to measure Q393 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.58. Immunizations for Adolescents

Category	Description
NQF # / eCQM NQF #:	1407
Quality #:	394
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/ Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.
Substantive Change:	**Updated denominator exclusions:** Added exclusion for encephalopathy due to Tdap vaccine. **Updated numerator to specify compliant serogroups:** Serogroups A, C, W, Y
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed the denominator exclusion be expanded to include encephalopathy as an eligible reason to exclude the patient from the Tdap vaccine clinical action. Both Adacel® and Boostrix® list progressive or unstable neurologic conditions, which would include encephalopathy, as reasons to defer their administration. The numerator was updated to specify the required serogroup. According to the Centers for Disease Control, all 11 to 12 year olds should be vaccinated with a meningococcal conjugate vaccine (Serogroups A, C, W, Y), with a booster dose given at 16 years old. All teens may also be vaccinated with a serogroup B meningococcal vaccine, preferably at 16 through 18 years old. This measure is assessing a younger patient population. We agree with adding specificity to the numerator to align with the current guidelines.
We received no comments on the substantive changes proposed for measure Q394: Immunization for Adolescents. Therefore, we are finalizing the changes to measure Q394 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.59. Appropriate Follow-up Imaging for Incidental Abdominal Lesions

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	405
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for abdominal imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended • Liver lesion ≤ 0.5 cm. • Cystic kidney lesion < 1.0 cm. • Adrenal lesion ≤ 1.0 cm.
Substantive Change:	**Updated measure assessment:** The measure analytic is being updated and will no longer be inverse. **The measure description is revised to read:** Percentage of final reports for abdominal imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion ≤ 1.0 cm • Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **The denominator is revised to read:** All final reports for imaging studies for patients aged 18 years and older with one or more of the following incidentally noted: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion ≤ 1.0 cm • Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **Updated denominator note: For the MIPS CQMs Specifications collection type:** Updated to include changes in the denominator and to include: *Other "simple-appearing criteria": • Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017) • Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017) Radiologists may choose not to include in the radiology report benign-appearing renal cysts (Bosniak I or II or equivalent*) or cystic lesions that are too small to characterize (TSTC) but likely benign (a lesion is too small to characterize (TSTC) when the lesion size is less than twice reconstructed slice thickness (ACR, 2017). **Updated denominator: For the MIPS CQMs Specifications collection type:** Updated criteria: Incidental finding: Cystic renal lesion that is simple appearing* (Bosniak I or II), or Adrenal lesion ≤ 1.0 cm or Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** Updated to include changes in the denominator and to include: *Other "simple-appearing criteria": • Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017) • Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017) Radiologists may choose not to include in the radiology report benign-appearing renal cysts (Bosniak I or II or equivalent*) or cystic lesions that are too small to characterize (TSTC) but likely benign (a lesion is too small to characterize (TSTC) when the lesion size is less than twice reconstructed slice thickness (ACR, 2017). **Updated numerator instructions:** Removed inverse measure instructions. Added: A short note can be made in the final report, such as: "No follow-up imaging is recommended as incidental lesions are likely benign " or "No follow-up imaging is recommended per consensus recommendations based on imaging criteria. Further lab evaluation could be pursued based on clinical findings" **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications collection type:** Updated to reflect the changes to what is considered an incidental lesion.

Category	Description
	The numerator is revised to read: Final reports for imaging studies that include a description of incidental cystic renal lesion or adrenal lesion stating follow-up imaging is not recommended. **Updated numerator options:** Updated to reflect changes to the analytics of the measure and what is considered an incidental lesion. **Updated denominator exception:** Updated to read: Documentation of medical reason(s) that follow-up imaging is indicated (e.g., patient has lymphadenopathy, signs of metastasis or an active diagnosis or history of cancer, and other medical reason(s).
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update all aspects of this measure based upon the American College of Radiology's Technical Expert Panel (TEP) recommendations in order to bring the measure into alignment with current guidelines. The measure analytic is also being updated so that it is no longer an inverse measure. In addition, liver lesions have been removed from the denominator and the denominator exception has been updated to reflect the intent of the measure. We agree with these changes as they will bring the measure in better alignment with current clinical guidelines. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

We proposed a substantive change to the description and denominator; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:

The measure description is revised to read for the MIPS CQMs Specifications and Medicare Part B claims collection type:

Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings:

- Cystic renal lesion that is simple appearing* (Bosniak I or II)
- Adrenal lesion less than or equal to 1.0 cm
- Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols

This additional refinement does not affect the intent of the proposed substantive change and aligns the language throughout the specification. Additionally, during the annual revision process the measure steward replaced all symbols (e.g., <, >, ≤) referencing lesion size with wording for clarification. This additional refinement was to ensure clarity in language so that there is consistency in the language of the specification and does not affect the intent of the proposed substantive change.

The denominator is revised to read for the MIPS CQMs and Medicare Part B claims collection types:

All final reports for imaging studies for patients aged 18 years and older with one or more of the following incidentally noted:

- Cystic renal lesion that is simple appearing *(Bosniak I or II)*
  or
- Adrenal lesion less than or equal to 1.0 cm
  or
- Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols

This additional refinement does not affect the intent of the proposed substantive change and aligns the language throughout the specification. Additionally, during the annual revision process the measure steward replaced all symbols (e.g., <, >, ≤) referencing lesion size with wording for clarification. This additional refinement was to ensure clarity in language so that there is consistency in the language of the specification and does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:

Updated denominator note: For the MIPS CQMs Specifications collection type: Updated to include changes in the denominator and to include:

*Other "simple-appearing criteria":

• Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017)

• Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017)

Radiologists may choose not to include in the radiology report benign-appearing renal cysts (Bosniak I or II or equivalent*) or cystic lesions that are too small to characterize (TSTC) but likely benign (a lesion is too small to characterize (TSTC) when the lesion size is less than twice reconstructed slice thickness (ACR, 2017).

Updated denominator: For the MIPS CQMs Specifications collection type: Updated criteria:

Incidental finding: Cystic renal lesion that is simple appearing* (Bosniak I or II), or Adrenal lesion ≤ 1.0 cm or Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols

Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type: Updated to include changes in the denominator and to include:

*Other "simple-appearing criteria":

Category	Description
• Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017) • Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017) Radiologists may choose not to include in the radiology report benign-appearing renal cysts (Bosniak I or II or equivalent*) or cystic lesions that are too small to characterize (TSTC) but likely benign (a lesion is too small to characterize (TSTC) when the lesion size is less than twice reconstructed slice thickness (ACR, 2017). **Updated numerator instructions:** Removed inverse measure instructions. Added: A short note can be made in the final report, such as: "No follow-up imaging is recommended as incidental lesions are likely benign " or "No follow-up imaging is recommended per consensus recommendations based on imaging criteria. Further lab evaluation could be pursued based on clinical findings" **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications collection type:** Updated to reflect the changes to what is considered an incidental lesion. We received no comments on the substantive changes proposed for measure Q405: Appropriate Follow-Up Imaging for Incidental Abdominal Lesions. Therefore, we are finalizing the changes to measure Q405 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.	

D.60. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	415
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care clinician who have an indication for a head CT.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications **Update description:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT. **Update denominator exclusions:** Removed pregnancy and revised list of antiplatelets applicable to the exclusion.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type. The benchmarking data shows that this measure is meets the extremely topped out definition for the Medicare Part B Claims Measure Specification collection type. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type. Additionally, we proposed the denominator exclusions be updated to remove pregnancy as an eligible exclusion due to the low count of exclusion instances, and the list of antiplatelets was revised based upon an in depth review by the quality measures committee and measure leads and now aligns more closely with the current clinical workflow. The description was updated to align with the measure language throughout the specification.
We received no comments on the substantive changes proposed for measure Q415: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older. Therefore, we are finalizing the changes to measure Q415 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.61. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.
Substantive Change:	**Updated denominator exclusions:** Removed thrombocytopenia.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed due to the low count of exclusion instances, to remove thrombocytopenia from the list of eligible denominator exclusions.
We received no comments on the substantive changes proposed for measure Q416: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years. Therefore, we are finalizing the changes to measure Q416 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.62. Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053
Quality #:	418
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator exclusions**: Updated: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. Added: (1) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (3) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed and agree with the measure steward that the denominator exclusions be updated because it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services. We are also proposing to update the exclusion for living long term in an institution to include the criteria for more than 90 days during the measurement period. We agree with the measure steward as this would ensure the correct patient population is being removed from the eligible population and will lessen the burden to submit data for these MIPS eligible clinicians.
Comment: One commenter opposed not implementing the exclusion for adults 80 and older with frailty for measure Q418: Osteoporosis Management in Older Women Who Had a Fracture. This exclusion is critical for focusing the measures on the population most likely to benefit from the measured services. Without this exclusion, these measures will be out of alignment with what is required for reporting. **Response:** We thank the commenter for their comment, however this revision was not proposed and would be considered a substantive change. We believe introducing this concept without collaboration and clarification with the measure steward may create implementation variability for eligible clinicians. Therefore, we would encourage the commenter to work with the measure steward to incorporate this revision for future years. After consideration of the comments, we are finalizing the changes to measure Q418 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.63. Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	438
CMS eCQM ID:	CMS347v3
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.
Substantive Change:	**Updated denominator exception:** Added hospice care.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward proposed to add patients receiving hospice care to the eligible denominator exceptions to align with the intent of the measure. We agree with the measure steward that this patient population should be removed as patients in hospice care would not benefit from this clinical service and we believe that by removing this patient population it will reduce the burden of submission for these MIPS eligible clinicians providing care to these patients.

Comment: One commenter reviewed the proposed changes to the CMS Web Interface Measure Specification collection type for measure Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease and believed there are impacts to the benchmarks and a need to provide pay-for-reporting for 2019 and 2020 MIPS performance periods.

Response: We thank the commenter for their comment. Under MIPS, there is no pay-for-reporting option. In these instances, we exclude the measure from MIPS scoring for the CMS Web Interface Measures Specification collection type in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement for the impacted performance period. For this substantive change, we disagree with the commenter that the measure should be excluded from MIPS scoring for the 2019 MIPS performance period as these revisions will be implemented for the 2020 MIPS performance period and do not affect the 2019 MIPS performance period. Additionally, we do not believe that the revisions necessitate an updated benchmark for the MIPS 2020 performance period as the updated denominator exception for hospice care does not significantly impact measure Q438 and allows for direct comparison of performance data from prior years.

Comment: One commenter requested that the denominator exclusions added for measure Q113: Colorectal Cancer Screening, measure Q112: Breast Cancer Screening, measure Q001: Diabetes A1c Poor Control, and measure Q236: Hypertension, Controlling High Blood pressure, also be added to ACO-42 (measure Q438), Statin Therapy for Treatment of Cardiovascular Disease measures. The commenter also requested that the age restriction is removed from these exclusions, as many of these interventions are not clinically appropriate in those with frailty and limited life expectancy due to advanced illness, regardless of age. The commenter recommended the following exclusion: Add Frailty, Dementia, and Advanced Illness in a Long-Term Care Setting.

Response: We thank the commenter for their comment and encourage them to reach out to the measure steward and collaborate with them regarding inclusion of these denominator exclusions.

After consideration of the comments, we are finalizing the changes to measure Q438 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.

D.64. Age Appropriate Screening Colonoscopy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	439
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.
Substantive Change:	**Updated denominator:** Removed exclusion for modifiers 52, 53, 73, and 74.
Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed that the denominator be expanded to include coded colonoscopy procedures that are indicated as incomplete or discontinued with modifiers 52, 53, 73, or 74 as denominator eligible. We agree that these procedures should be included in the denominator as the measure is looking to assess whether a colonoscopy was clinically indicated for the patient. Even if the colonoscopy was indicated as incomplete or discontinued, we would want that instance included in the denominator to determine if there was a valid medical reason for it to be performed.

We received no comments on the substantive changes proposed for measure Q439: Age Appropriate Screening Colonoscopy. Therefore, we are finalizing the changes to measure Q439 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.

D.65. Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	440
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.
Substantive Change:	**The measure title is revised from Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician to read:** Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician. **The measure description is revised to read:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC), Squamous Cell Carcinoma (SCC) (including in situ disease), or melanoma in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist. **Updated denominator:** Added melanoma diagnosis codes. **Updated numerator:** Included language to reflect the addition of melanoma to the denominator.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed that the denominator be expanded to include melanoma diagnosis codes. The measure steward believes this will allow for a broader patient population to reflect communication and care coordination of skin cancers, not just non-melanoma skin cancer. The measure title, description, denominator, and numerator language is being updated to align with the inclusion of a melanoma diagnosis.

Comment: One commenter supported the substantive changes to measure Q440: Basal Cell Carcinoma (BCC)!Squamous Cell Carcinoma (SCC): Biopsy Reporting Time- Pathologist to Clinician impacting the measure title, description, and numerator/denominator as these changes are consistent with recommendations by the measure steward.

Another commenter supported the changes to Q440, but stated there is an error in the description. This is the measure as it was approved: "Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC), Squamous Cell Carcinoma (SCC), **or melanoma** (including in situ disease), ~~or melanoma~~ in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist."

Response: We thank the commenters for supporting the revision to measure Q440. We agree that the description needed revised to align with the intent of the measure, and have reflected this update.

We proposed a substantive change to the description; however, during public comment it was noticed that the title was not updated to align with revisions being made to measure. Based on this comment, there was additional language refinement to state:

The measure description is revised to read: Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist. This additional refinement does not affect the intent of the proposed substantive change. This additional refinement was to ensure clarity and consistency within the measure and does not affect the intent of the proposed substantive change.

There were no additional refinements to substantive changes:
The measure title is revised from Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician to read: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician.

Updated denominator: Added melanoma diagnosis codes.

Updated numerator: Included language to reflect the addition of melanoma to the denominator.

After consideration of the comments, we are finalizing the changes as indicated to measure Q440 for the 2020 MIPS performance period/2022 MIPS payment year and future years.

D.66. Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	441
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated
Substantive Change:	**Updated denominator exceptions:** Added Procedure-Related BP's not taken during an outpatient visit. Examples of Procedure-related BP Locations: Same Day Surgery, Ambulatory Service Center, G.I. Lab, Dialysis, Infusion Center, Chemotherapy.
Steward:	Wisconsin Collaborative for Healthcare Quality (WCHQ)
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed and agree with the WCHQ Measurement Advisory Committee that procedure-related blood pressures should be excluded from this measure. We agree with the inclusion of the denominator exception as procedure-related blood pressures can be artificially elevated. This change also aligns with other blood pressure related measure exclusions.
We received no comments on the substantive changes proposed for measure Q441: Ischemic Vascular Disease (IVD) All of None Outcome Measure (Optimal Control). Therefore, we are finalizing the changes to measure Q441 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.67. Appropriate Workup Prior to Endometrial Ablation

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	448
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of women, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results documented before undergoing an endometrial ablation.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation. **Updated denominator:** Replace the word "women" with "patients". **Updated numerator:** Replace the word "women" with "patients".
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure description to read "percentage of patients" in order to be gender inclusive. This change will also be reflected throughout the measure for consistency.
We received no comments on the substantive changes proposed for measure Q448: Appropriate Workup Prior to Endometrial Ablation. Therefore, we are finalizing the changes to measure Q448 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.68. Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy

Category	Description
NQF # / eCQM NQF #:	1858
Quality #:	450
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab.
Substantive Change:	**Updated denominator definition:** Use the 2018 ASCO/CAP guideline definitions to determine HER2 status- HER2 Positive: • If result is IHC 3+ based on circumferential membrane staining that is complete, intense and in >10% of the invasive tumor cells • If result is ISH positive based on: • Single-probe average HER2 copy number ≥= 6. 0 signals/cell • Dual-probe HER2/CEP17 ratio ≥= 2. 0 with an average HER2 copy number ≥= 4. 0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number = 6. 0 signals/cell HER2 Equivocal: • If result is IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate and within > 10% of the invasive tumor cells • If result is ISH equivocal based on: • Single-probe ISH average HER2 copy number ≥= 4. 0 and < 6. 0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number ≥= 4. 0 and < 6. 0 signals/cell HER2 Negative: • If result is IHC 1+ based on incomplete membrane staining that is faint/barely perceptible and within > 10% of the invasive tumor cells • If result is IHC 0 based on no staining observed or membrane staining that is incomplete and is faint/barely perceptible and ≤= 10% of the invasive tumor cells • ISH negative based on: • Single-probe average HER2 copy number < 4. 0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number < 4. 0 signals/cell HER2 Indeterminate: Report HER2 test result as indeterminate if technical issues prevent one or both tests (IHC and ISH) from being reported as positive, negative, or equivocal. Conditions may include: • Inadequate specimen handling • Artifacts (crush or edge artifacts) that make interpretation difficult • Analytic testing failure.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator definition so that it aligns with the 2018 ASCO/CAP guidelines.

Category	Description
We proposed a substantive change to the denominator definition; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state: **Updated denominator definition:** Use the 2018 ASCO/CAP guideline definitions to determine HER2 status- HER2 Positive: • If result is IHC 3+ based on circumferential membrane staining that is complete, intense and in >10% of the invasive tumor cells • If result is ISH positive based on: • Single-probe average HER2 copy number ≥ 6.0 signals/cell • Dual-probe HER2/CEP17 ratio ≥ 2. 0 with an average HER2 copy number ≥ 4.0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number = 6.0 signals/cell HER2 Equivocal: • If result is IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate and within > 10% of the invasive tumor cells • If result is ISH equivocal based on: • Single-probe ISH average HER2 copy number ≥ 4.0 and < 6.0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number ≥4.0 and < 6.0 signals/cell HER2 Negative: • If result is IHC 1+ based on incomplete membrane staining that is faint/barely perceptible and in > 10% of the invasive tumor cells • If result is IHC 0 based on no staining observed or membrane staining that is incomplete and is faint/barely perceptible and in ≤ 10% of the invasive tumor cells • ISH negative based on: • Single-probe average HER2 copy number < 4.0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number < 4.0 signals/cell HER2 Indeterminate: Report HER2 test result as indeterminate if technical issues prevent one or both tests (IHC and ISH) from being reported as positive, negative, or equivocal. Conditions may include: • Inadequate specimen handling • Artifacts (crush or edge artifacts) that make interpretation difficult • Analytic testing failure. This additional refinement was to ensure clarity in language for eligible clinicians that chose to implement measure Q450 and does not affect the intent of the proposed substantive change. We received no comments on the substantive changes proposed for measure Q450: Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy. Therefore, we are finalizing the changes to measure Q450 with the exception of removing duplication of symbols (that is, update ≥= to ≥) for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.	

D.69. Back Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	459
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had a lumbar discectomy /laminotomy procedure.
Substantive Change:	**The measure title is revised from Average Change in Back Pain Following Lumbar Discectomy / Laminotomy to read:** Back Pain After Lumbar Discectomy/Laminectomy. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated denominator:** Added discectomy/ laminectomy CPT procedure codes: 63005, 63012, 63017, 63030, 63042 and 63047. Removed diagnosis of disc herniation. **Updated denominator exclusions:** Added spine related cancer, acute fracture or infection, neuromuscular, idiopathic or congenital scoliosis. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op pain assessment is greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being back pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at 3 months postoperatively (6 to 20 weeks). **Updated definitions:** Added: (1) Back Pain Target #1 - A patient who is assessed postoperatively at three months (6 to 20 weeks) after the procedure who rates their back pain as less than or equal to 3.0. (2) Back Pain Target #2 - A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the change is greater than or equal to 5.0 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9943 is submitted. • VAS Pain Scale is not administered postoperatively at three months (6 to 20 weeks) • Back pain is measured using a different patient reported tool or via telephone screening • Postoperative VAS Pain Scale is administered less than six weeks or more than 20 weeks (3 month window) • Postoperative VAS value is greater than 3.0 and no valid preoperative to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We proposed that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward chose the targets based on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. The measure steward's measure development workgroup reached a consensus to expand the denominator to more broadly include all patients undergoing discectomy/laminectomy procedures by removing the diagnosis of disc herniation and adding procedure codes. As a part of this decision, it was decided to add a denominator exclusion as the measure steward believes this will help to create a more heterogeneous population. We agree with the expansion of the denominator to capture all patients undergoing discectomy/laminectomy procedures. Additionally, the definitions and the numerator note were proposed to be updated to align with the other changes and to add clarity. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.
The measure steward has postponed the inclusion of spine related neuromuscular conditions in order to continue testing and implement this concept consistently through all similar measure concepts within MIPS. As such we will not be finalizing the spine related neuromuscular conditions denominator exclusion. We are finalizing the denominator exclusion to include: Spine related cancer, acute fracture or infection, idiopathic or congenital scoliosis. Additionally, we proposed a substantive change to the definitions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the Back Pain Target #2 substantive change to state: A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the improvement is greater than or equal to 5.0 points. This additional refinement does not affect the intent of the proposed substantive change and aligns with the measure language. We received no comments on the substantive changes proposed for measure Q459: Back Pain After Lumbar Discectomy/Laminectomy. Therefore, we are finalizing the changes to measure Q459 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the exception of the denominator exclusion.	

D.70. Back Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	460
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had a lumbar fusion procedure.
Substantive Change:	**The measure title is revised from Average Change in Back Pain Following Lumbar Fusion to read:** Back Pain After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being back pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at one year postoperatively (9 to 15 months). **Updated definitions:** Added: (1) Back Pain Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their back pain as less than or equal to 3.0. (2) Back Pain Target #2 – A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the change is greater than or equal to 5.0 points. **Updated numerator note;** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9946 is submitted. • VAS Pain Scale is not administered postoperatively at one year (9 to 15 months) • Back pain is measured using a different patient reported tool or via telephone screening • Postop VAS Pain Scale is administered less than nine months or more than 15 months (1 year window) • Postoperative VAS value is greater than 3.0 and no valid preop to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward base the target on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is ≤2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. Additionally, the definitions and the numerator note were proposed to be updated to align with the other changes and to add clarity. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

Category	Description
We proposed a substantive change to the definitions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the Back Pain Target #2 substantive change to state: **Updated definitions:** Added: (2) Back Pain Target #2: A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the improvement is greater than or equal to 5.0 points. This additional refinement was to ensure clarity in language support understanding in the guidance to implement quality measure Q460 and does not affect the intent of the proposed substantive change. There were no additional refinements to substantive changes: **The measure title is revised from Average Change in Back Pain Following Lumbar Fusion to read:** Back Pain After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being back pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at one year postoperatively (9 to 15 months). **Updated definitions:** Added: (1) Back Pain Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their back pain as less than or equal to 3.0. **Updated numerator note;** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9946 is submitted. • VAS Pain Scale is not administered postoperatively at one year (9 to 15 months) • Back pain is measured using a different patient reported tool or via telephone screening • Postop VAS Pain Scale is administered less than nine months or more than 15 months (1 year window) • Postoperative VAS value is greater than 3.0 and no valid preop to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure) We received no comments on the substantive changes proposed for measure Q460: Back Pain After Lumbar Fusion. Therefore, we are finalizing the changes to measure Q460 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.	

D.71. Leg Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	461
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.
Substantive Change:	**The measure title is revised from Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy to read:** Leg Pain After Lumbar Discectomy/Laminectomy. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated denominator:** Added the following discectomy/ laminectomy CPT procedure codes: 63005, 63012, 63017, 63030, 63042 and 63047. Removed diagnosis of disc herniation. **Updated denominator exclusions:** Added spine related cancer, acute fracture or infection, neuromuscular, idiopathic or congenital scoliosis. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being leg pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at 3 months postoperatively (6 to 20 weeks). **Updated definitions:** Added: (1) Leg Pain Target #1 - A patient who is assessed postoperatively at three months (6 to 20 weeks) after the procedure who rates their leg pain as less than or equal to 3.0. (2) Leg Pain Target #2 - A patient who does not meet Leg Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the change is greater than or equal to 5.0 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9949 is submitted. • VAS Pain Scale is not administered postoperatively at three months (6 to 20 weeks) • Leg pain is measured using a different patient reported tool or via telephone screening • Postoperative VAS Pain Scale is administered less than six weeks or more than 20 weeks (3 month window) • Postoperative VAS value is greater than 3.0 and no valid preop to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We proposed that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward based the target on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0.We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. The measure steward's measure development workgroup reached a consensus to expand the denominator to more broadly include all patients undergoing discectomy/laminectomy procedures by removing the diagnosis of disc herniation and adding procedure codes. As a part of this decision, it was decided to add a denominator exclusion as the measure steward believes this will help to create a more heterogeneous population. We agree with the expansion of the denominator to capture all patients undergoing discectomy/laminectomy procedures. Additionally, the definitions and the numerator note were proposed to be updated to align with the other changes and to add clarity. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.
The measure steward has postponed the inclusion of spine related neuromuscular conditions in order to continue testing and implement this concept consistently through all similar measure concepts within MIPS. As such, we will not be finalizing the spine related neuromuscular conditions denominator exclusion. We are finalizing the denominator exclusion to include: Spine related cancer, acute fracture or infection, idiopathic or congenital scoliosis. Additionally, we proposed a substantive change to the definitions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the Leg Pain Target #2 substantive change to state: A patient who does not meet Leg Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the improvement is greater than or equal to 5.0 points. This additional refinement does not affect the intent of the proposed substantive change and aligns with the measure language. We received no comments on the substantive changes proposed for measure Q461: Leg Pain After Lumbar Discectomy/Laminectomy. Therefore, we are finalizing the changes to measure Q461 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the exception of the denominator exclusion.	

D.72. Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	462
CMS eCQM ID:	CMS645v3
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater (indicated by HCPCS code) and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**The measure description is revised to read:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description to align with the removal of the custom HCPCS, J code J1950, which previously denoted the practitioner's intent of androgen deprivation therapy (ADT) for a period of 12 months or greater. The intent of the measure remains intact, but no longer requires the HCPCS to identify the intended patient population.
We received no comments on the substantive changes proposed for measure Q462: Bone Density for Patients with Prostate Cancer and Receiving Androgren Deprivation Therapy. Therefore, we are finalizing the changes to measure Q462 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years	

D.73. Functional Status After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	469
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients 18 years of age and older who had a lumbar fusion procedure.
Substantive Change:	**The measure title is revised from Average Change in Functional Status Following Lumbar Fusion Surgery to read:** Functional Status After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 22, need a pre and post-op assessment to hit the change target of 30 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being functional status is less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI) at one year postoperatively (9 to 15 months). **Added numerator definition:** Functional Status Target #1 - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status as less than or equal to 22. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the change is greater than or equal to 30 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative tool be administered to the patient to increase the chance that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1043 is submitted. • ODI is not administered postoperatively at one year (9 to 15 months) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 9 months or greater than 15 months (1 year window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure change • Preoperative ODI (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure.) NQF endorsement removed until the measure can be evaluated with the new analytics.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward based the target on a study Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine-a Spine Tango registry-based study. vanHooff, ML et al Spine J. 2016 Oct;16 (10):1221-1230. Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op ODI to determine an equivalent ODI threshold. ODI score less than or equal to 22 indicates the achievement of an acceptable symptom state and can be used as a criterion for treatment success. [AUC]: 0.89 [sensitivity: 78.3%, specificity: 82.1%] for 1 year follow-up]. The OR benchmark of change (30) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 22. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. Additionally, the definitions and the numerator note were proposed to be updated to align with the other changes and to add clarity. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.
We received no comments on the substantive changes proposed for measure 469: Functional Status After Lumbar Fusion. Therefore, we are finalizing the changes to measure Q469 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years	

D.74. Functional Status After Primary Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	470
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to postoperative) in functional status using the Oxford Knee Score (OKS) for patients age 18 and older who had a primary total knee replacement
Substantive Change:	**The measure title is revised to read:** Functional Status After Primary Total Knee Replacement. **The measure description is revised:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need a post-op OKS assessment. The measure will now be target-based with performance met being functional status is greater than or equal to 37 on the Oxford Knee Score (OKS) at one year postoperatively (9 to 15 months). Patients who are missing an assessment will be considered numerator non-compliant. **Added numerator definition:** OKS Target - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status score as greater than or equal to 37. **Updated numerator note:** The following situations are those in which the numerator targets cannot be reached and Performance Not Met (M1046) is submitted: • Oxford Knee Score (OKS) is not administered postoperatively at one year (9 to 15 Months) • Functional status is measured using a different patient-reported functional status tool or Oxford Knee Score (OKS) version • Postoperative Oxford Knee Score (OKS) is administered less than 9 Months or greater than 15 Months • Postoperative Oxford Knee Score (OKS) score is less than 37 NQF endorsement removed until the measure can be evaluated with the new analytics.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed that this measure assessment will be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward derived the target from a study "Patient acceptable symptom states after total hip or knee replacement at mid-term follow-up" [Kuerentjes JC, Van Tol FR Bone Joint Res 2014; 3:7–13]. Receiver operating characteristic (ROC) curves identified a PASS threshold of 42 for the OHS after THR and 37 for the OKS after TKR. THR patients with an OHS greater than or equal to 42 and TKR patients with an OKS greater than or equal to 37 had a higher NRS for satisfaction and a greater likelihood of being willing to undergo surgery again. The Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op OKS to determine an equivalent OKS threshold. OKS score greater than or equal to 37 indicates the achievement of an acceptable symptom state and correlates with a higher numeric rating scale for satisfaction [ROC curves PASS threshold of 37 with sensitivity of 76.3% and specificity of 76.5%]. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. Additionally, the definitions and the numerator note were proposed to be updated to align with the other changes and to add clarity. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.
We received no comments on the substantive changes proposed for measure Q470: Functional Status After Primary Total Knee Replacement. Therefore, we are finalizing the changes to measure Q470 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years	

D.75. Functional Status After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	471
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients age 18 and older who had lumbar discectomy/laminotomy procedure
Substantive Change:	**The measure title is revised from Average Change in Functional Status Following Lumbar Discectomy/Laminotomy Surgery to read:** Functional Status After Lumbar Discectomy/Laminectomy. **The measure description is revised to read:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated denominator:** Added the following discectomy/ laminectomy CPT procedure codes: 63005, 63012, 63017, 63030, 63042 and 63047. **Update denominator exclusions:** Added spine related cancer, acute fracture or infection, neuromuscular, idiopathic or congenital scoliosis. Removed diagnosis of disc herniation. **Updated numerator:** For numerator compliance patients need either a post-op functional assessment (to meet the target portion) or if post-op greater than 22, need a pre and post-op assessment to hit the change target of 30 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being functional status is less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI) at 3 months postoperatively (6 to 20 weeks). **Added numerator definition:** Functional Status Target #1 - A patient who is assessed postoperatively at three months (6 to 20 weeks) after the procedure rates their functional status as less than or equal to 22. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the change is greater than or equal to 30 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative be administered to the patient increasing chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1049 is submitted. • ODI is not administered postoperatively at three months (6 to 20 weeks) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 6 weeks or greater than 20 weeks (3 month window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure change Preoperative ODI (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We proposed that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward derived the target from a study Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine-a Spine Tango registry-based study. vanHooff, ML et al Spine J. 2016 Oct;16(10):1221-1230. Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op ODI to determine an equivalent ODI threshold. ODI score less than or equal to 22 indicates the achievement of an acceptable symptom state and can be used as a criterion for treatment success. [AUC]: 0.89 [sensitivity: 78.3%, specificity: 82.1%] for 1 year follow-up]. The OR benchmark of change (30) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 22. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. The measure steward's measure development workgroup reached a consensus to expand the denominator to more broadly include all patients undergoing discectomy/laminectomy procedures by removing the diagnosis of disc herniation and adding procedure codes. As a part of this decision, it was decided to add a denominator exclusion as the measure steward believes this will help to create a more heterogeneous population. We agree with the expansion of the denominator to capture all patients undergoing discectomy/laminectomy procedures. Additionally, the definitions and the numerator note were proposed to be updated to align with the other changes and to add clarity. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.
The measure steward has postponed the inclusion of spine related neuromuscular conditions in order to continue testing and implement this concept consistently through all similar measure concepts within MIPS. As such, we will not be finalizing the spine related neuromuscular conditions denominator exclusion. We are finalizing the denominator exclusion to include: Spine related cancer, acute fracture or infection, idiopathic or congenital scoliosis. We received no comments on the substantive changes proposed for measure Q471: Functional Status After Lumbar Discectomy/Laminectomy. Therefore, we are finalizing the changes to measure Q471 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the exception of the denominator exclusion.	

D.76. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	472
CMS eCQM ID:	CMS249v2
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.

Category	Description
Substantive Change:	**Updated guidance:** There are two ways that a patient can be excluded from the measure: 1. The patient has a specific number of "combination" risk factors (the number of risk factors varies by age). 2. The patient has one or more of the "independent" risk factors, including a 10-year probability of major osteoporotic fracture of 8.4 percent or higher as determined by the FRAX. Denominator exclusions statement: Exclude patients with a combination of risk factors (as determined by age) or one of the independent risk factors Ages: 50-54 (>=4 combination risk factors) or 1 independent risk factor Ages: 55-59 (>=3 combination risk factors) or 1 independent risk factor Ages: 60-64 (>=2 combination risk factors) or 1 independent risk factor COMBINATION RISK FACTORS [The following risk factors are all combination risk factors; they are grouped by when they occur in relation to the measurement period]: The following risk factors may occur any time in the patient's history but must be active during the measurement period: White (race) BMI <= 20 kg/m2 (must be the first BMI of the measurement period) Smoker (current during the measurement period) Alcohol consumption (> two units per day (one unit is 12 oz. of beer, 4 oz. of wine, or 1 oz. of liquor)) The following risk factor may occur any time in the patient's history and must not start during the measurement period: Osteopenia The following risk factors may occur at any time in the patient's history or during the measurement period: Rheumatoid arthritis Hyperthyroidism Malabsorption Syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption Chronic liver disease Chronic malnutrition The following risk factors may occur any time in the patient's history and do not need to be active at the start of the measurement period: Documentation of history of hip fracture in parent Osteoporotic fracture Glucocorticoids (>= 5 mg/per day) [cumulative medication duration >= 90 days] INDEPENDENT RISK FACTORS (The following risk factors are all independent risk factors; they are grouped by when they occur in relation to the measurement period): The following risk factors may occur at any time in the patient's history and must not start during the measurement period: Osteoporosis The following risk factors may occur at any time in the patient's history prior to the start of the measurement period, but do not need to be active during the measurement period: Gastric bypass FRAX[R] ten-year probability of all major osteoporosis related fracture >= 8.4 percent Aromatase inhibitors The following risk factors may occur at any time in the patient's history or during the measurement period: Type I Diabetes End stage renal disease Osteogenesis imperfecta Ankylosing spondylitis Psoriatic arthritis Ehlers-Danlos syndrome Cushing's syndrome Hyperparathyroidism Marfan syndrome Lupus **Updated denominator exclusions:** Changed FRAX[R] ten-year probability of all major osteoporosis related fracture result from 9.3% to 8.4%.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process

Category	Description
Rationale:	We proposed that the denominator exclusion for the Fracture Risk Assessment Tool FRAX® ten-year probability of all major osteoporosis related fracture result be changed from 9.3% to 8.4% to align with the US Preventive Services Task Force (USPSTF) recommendations. We agree with this change as it keeps the measure in alignment with the current clinical guidelines. The guidance is being updated for better alignment with the measure and to align with the updated denominator exclusion.
We received no comments on the substantive changes proposed for measure Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture. Therefore, we are finalizing the changes to measure Q472 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.77. Leg Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	473
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to one year postoperative) in leg pain for patients 18 years of age or older who had a lumbar fusion procedure
Substantive Change:	**The measure title is revised from Average Change in Leg Pain Following Lumbar Fusion Surgery to read:** Leg Pain After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance Patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being leg pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at one year postoperatively (9 to 15 months).
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward based the target score on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of improvement (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. As finalized, the substantive changes do not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the minimum reliability requirements, a new benchmark will be generated.

Category	Description
Comment: One commenter requested that omitted text for measure Q473: Average Change in Leg Pain Following Lumbar Fusion Surgery be added to this measure. This text was included in the final measure specification but omitted from the 2020 PFS proposed rule (84 FR 41272). The substantive change in the proposed rule is correct with the additional language below to be added. Updated definitions: Added: (1) Leg Pain Target #1 A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their leg pain as less than or equal to 3.0. (2) Leg Pain Target #2 A patient who does not meet Leg Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the change is greater than or equal to 5.0 points. Updated numerator note: It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1052 is submitted. VAS Pain Scale is not administered postoperatively at one year (9 to 15 months) Leg pain is measured using a different patient reported tool or via telephone screening Postop VAS Pain Scale is administered less than nine months or more than 15 months (1 year window) Postoperative VAS value is greater than 3.0 and no valid preop to measure change Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure) **Response:** We thank the commenter for their consideration and agree this additional detail will aid in the clarification of implementation. We do encourage measure stewards to submit these substantive changes during the Call for Substantive Changes, which typically occurs at the beginning of each year. We proposed a substantive change to the Description; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain. This additional refinement was to ensure clarity in language so that the quality action is defined for measure Q473 and does not affect the intent of the proposed substantive change. There were no additional refinements to substantive changes: **The measure title is revised from Average Change in Leg Pain Following Lumbar Fusion Surgery to read:** Leg Pain After Lumbar Fusion. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance Patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being leg pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at one year postoperatively (9 to 15 months). After consideration of the comments, we are finalizing the changes to measure Q473 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years with the revisions noted above.	

D.78. HIV Screening

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	475
CMS eCQM ID:	CMS349v2
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 15-65 years of age who have been tested for HIV within that age range.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV. **The numerator is revised to read:** Patients with documentation of an HIV test performed on or after their 15th birthday and before their 66th birthday.
Steward:	Centers for Disease Control and Prevention
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description to better align the measure specification. We agree with this update as it clarifies the intent of the measure. We proposed that the numerator be revised to add clarity and to align the wording with logic used. Neither the intent of the measure nor the numerator action will be changed.
We received no comments on the substantive changes proposed for measure Q475: HIV Screening. Therefore, we are finalizing the changes to measure Q475 as proposed for the 2020 MIPS performance period/2022 MIPS payment year and future years.	

D.79. Dementia: Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	282
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.
Substantive Change:	**Updated denominator:** Added physical therapy MIPS eligible clinician type.
Steward:	American Psychiatric Association and American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	Based upon requests from measure steward physical therapy evaluation codes were proposed to be add to the denominator eligible encounters to allow for this measure to be used in an additional setting. We agree that this is a clinically relevant measure to the physical therapy setting.
After consideration of the comments received on this measure under Table C, we are finalizing the changes to measure Q282 as proposed (see 84 FR 41171) for the 2019 MIPS performance period/2021 MIPS payment year and future years because we did not finalize removal of this measure.	

D.80. Dementia: Education and Support of Caregivers for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	288
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
Substantive Change:	**Updated denominator:** Added physical therapy MIPS eligible clinician type.
Steward:	American Psychiatric Association and American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	Based upon requests from measure steward physical therapy evaluation codes were proposed to be add to the denominator eligible encounters to allow for this measure to be used in an additional setting. We agree that this is a clinically relevant measure to the physical therapy setting.
After consideration of the comments received on this measure under Table C, we are finalizing the changes to measure Q288 as proposed (see 84 FR 41171) for the 2019 MIPS performance period/2021 MIPS payment year and future years because we did not finalize removal of this measure.	

D.81. Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / 0041e
Quality #:	110
CMS eCQM ID:	CMS147v9
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**Updated numerator instructions:** Due to the changing nature of the CDC/ACIP recommendations regarding the live attenuated influenza vaccine (LAIV) for a particular flu season, this measure will not include the administration of this specific formulation of the flu vaccination. Given the variance of the timeframes for the annual update cycles, program implementation, and publication of revised recommendations from the CDC/ACIP, it has been determined that the coding for this measure will specifically exclude this formulation, so as not to inappropriately include this form of the vaccine for flu seasons when CDC/ACIP explicitly advise against it. However, it is recommended that all eligible professionals or eligible clinicians review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. If the LAIV is recommended for administration for a particular flu season, an eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting previous receipt, 2) report a denominator exception, either as a patient reason (e.g., for patient preference) or a system reason (e.g., the institution only carries LAIV).
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We agree with the update to the numerator instructions as it would allow for shared decision making between the patient and the eligible clinician, as well as align with the current performance period's CDC/ACIP guidelines without negatively affecting clinicians providing LAIV.
After consideration of the comments received on this measure under Table C, we are finalizing the changes to measure Q110 as proposed (see 84 FR 41158) for the 2019 MIPS performance period/2021 MIPS payment year and future years because we did not finalize removal of this measure.	

D.82. Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	111
CMS eCQM ID:	CMS127v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.
Substantive Change:	**Updated denominator:** Added the skilled nursing facility and domiciliary settings.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator coding be expanded to include the skilled nursing facility and domiciliary settings as applicable settings. We agree with the measure steward's decision to expand this measure to include these MIPS eligible clinicians as it is clinically relevant to this setting.
After consideration of the comments received on this measure under Table C, we are finalizing the changes to measure Q111 as proposed (see 84 FR 41159) for the 2019 MIPS performance period/2021 MIPS payment year and future years because we did not finalize removal of this measure.	

D.83. Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	178
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.
Substantive Change:	**Numerator statement revised to read:** Patients for whom a standardized functional status assessment using an ACR-preferred, patient-reported functional status assessment tool was performed at least once within 12 months. **Updated definition:** **Functional Status Assessment:** This measure assesses if physicians are using a standardized descriptive or numeric scale, standardized questionnaire, or notation of tool to assessment of the impact of RA on patient activities of daily living. Examples of tools used to assess functional status include but are not limited to: Health Assessment Questionnaire (HAQ), Modified HAQ, HAQ-2, and American College of Rheumatology's Classification of Functional Status in Rheumatoid Arthritis. Functional status should be assessed using a measurement tool assigned preferred status by the ACR. The instruments listed are the ACR-preferred tools that fulfill the measure requirements: PROMIS Physical Function 10-item (PROMIS PF10a), Health Assessment Questionnaire-II (HAQ-II), and Multi-Dimensional Health Assessment Questionnaire (MD-HAQ).
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward proposed to update the measure to require the use of ACR-preferred functional status assessment tools for numerator compliance. According to the ACR's RA treatment guidelines, functional status assessment using a standardized, validated measure should be performed routinely for RA patients, at least once per year, but more frequently if disease is active. We agree that it is important to utilize the proper assessment to ensure that the patient is being accurately assessed which will aid in clinical decisions regarding ongoing care.

Comment: One commenter stated that the requested changes to be made to measure Q178 are incorrectly captured. It appears the language in the change request document was copied and pasted without regard to formatting, which provided a visualization of deletions and additions.
The requested changes should appear as follows:
o New numerator statement: Patients for whom a functional status assessment using an ACR-preferred, patient-reported functional status assessment tool was performed at least once within 12 months
o New numerator definition: Functional Status Assessment – This measure assesses if physicians are using a standardized tool to assess the impact of RA on patient activities of daily living. Functional status should be assessed using a measurement tool assigned preferred status by the ACR. The instruments listed are the ACR-preferred tools that fulfill the measure requirements:
§ PROMIS Physical Function 10-item (PROMIS PF10a)
§ Health Assessment Questionnaire-II (HAQ-II)
§ Multi-Dimensional Health Assessment Questionnaire (MD-HAQ)

Response: We appreciate the comment clarifying the substantive changes for measure Q178 and agree that these refinements to language add clarity.

We proposed a substantive change to the numerator statement and definition; however, during the quality measure annual revision process with the measure steward, there was additional language refinement to state:

Numerator statement is revised to read: Patients for whom a functional status assessment using an ACR-preferred, patient-reported functional status assessment tool was performed at least once within 12 months.

Updated definition:
Functional Status Assessment – This measure assesses if physicians are using a standardized tool to assess the impact of RA on patient activities of daily living. Functional status should be assessed using a measurement tool assigned preferred status by the ACR. The instruments listed are the ACR-preferred tools that fulfill the measure requirements:
- PROMIS Physical Function 10-item (PROMIS PF10a)
- Health Assessment Questionnaire-II (HAQ-II)
- Multi-Dimensional Health Assessment Questionnaire (MD-HAQ)

These additional refinements were to ensure clarity in numerator assessment and how numerator compliance can be met for measure Q178 and does not affect the intent of the proposed substantive change.

After consideration of the comments received on this measure under Table C, we are finalizing the changes to measure Q178 as proposed (see 84 FR 41164) for the 2019 MIPS performance period/2021 MIPS payment year and future years because we did not finalize removal of this measure.

TABLE Group DD: Previously Finalized Quality Measures with Substantive Changes Finalized for the 2021 MIPS Payment Year and Future Years

NOTE: Electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table DD as follows: NQF # / eCQM NQF #.

DD.1. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / ECQM NQF #:	0028 / 0028e
Quality #:	226
CMS eCQM ID:	CMS138v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.
Substantive Change:	**Updated numerator guidance: for the 2019 performance period: For the CMS Web Interface Measure Specification collection type:** Removed "and the cessation intervention must occur during or after the most recent tobacco user status is documented" language from the guidance.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the numerator guidance in the CMS Web Interface Measure Specifications collection type for the 2019 performance period to remove the guidance given regarding the timing of the tobacco cessation intervention as this does not align with the intent of the measure. The refinements are in alignment with the clinical guidelines and will decrease burden for eligible clinicians performing tobacco screening and tobacco cessation intervention. The timing refinement proposed would maintain the balance of clinical guideline and measure alignment and support our effort to reduce burden for measure submission. Additionally, this timing refinement would allow the clinician to create personalized, patient-centered care while still maintaining the clinical integrity of the measure and clinical guidelines. To the extent this proposed change constituted a change in methodology after the start of the 2019 MIPS performance period, we stated that we believe that consistent with section 1871(e)(1)(A)(ii) of the Social Security Act, it would be contrary to the public interest not to modify the measure because the current guidance is inconsistent with the intent of the CMS Web Interface version of this measure and unduly burdensome for clinicians. The proposal was to update the CMS Web Interface Measure Specifications collection type numerator guidance previously stated in the current posted 2019 measure specification for PREV-10 (NQF #0028): Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, available at https://qpp.cms.gov/about/resource-library, in response to extensive stakeholder feedback regarding the timeframe during which the tobacco cessation intervention must occur. Specifically, stakeholders expressed concern that this additional language would not be comparable to the historic benchmark as it changed how the quality action of tobacco cessation intervention was abstracted in terms of numerator compliance. Additionally, stakeholders voiced concern regarding how this change would fit into the current clinical workflow as patients are asked about tobacco use on most if not all encounters, but clinicians do not feel it is necessary to provide tobacco cessation intervention at all encounters especially if it was already completed earlier in the year. Based on this feedback and our review, we explained that we had determined that the previously stated guidance is inconsistent with the intent of the CMS Web Interface Measure Specifications collection type version of this measure and unduly burdensome for clinicians. In response to our determination and stakeholder feedback, we proposed to update the CMS Web Interface Measure Specifications collection type numerator guidance to clarify that screening for tobacco use and tobacco cessation intervention do not have to occur on the same encounter, but must occur during the 24-month look-back period. We agree this proposal would maintain clinical intent, provide clarity, reduce clinician burden, and allow for personalized care.

Category	Description
Comment: Two commenters supported the substantive change to the Web Interface for measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention as corrected for the 2019 Performance Period. However, one commenter stated that if CMS is not fully confident that the logic and data collected in previous years for this metric matches the proposed logic and data to be collected, this metric should be Reporting Only in 2019, or at the very least, have the decile benchmarks revert back to 30, 40, 50, 60, 70, 80, and 90. With respect to ACO-17, Smoking Cessation (MIPS measure Q226), one commenter applauded CMS for making this measure pay-for-reporting in 2018 as it had requested. The commenter reiterated that this measure should be made pay-for-reporting in 2019 as well given the impact of measure specification changes and resulting effect on the benchmarks for this measure. The commenter urged CMS to finalize changes to the measure specification numerator requirements which better reflect clinical guidelines. Another commenter indicated that the revisions to measure Q226 were proposed to take effect starting in the 2019 reporting year for the CMS Web Interface Specifications collection type but apply starting in the 2020 reporting year for the eCQM Specifications collection type. Because of this difference, healthcare organizations that report using both collection types, such as organizations where some providers report as part of an APM and other providers report as individual eligible clinicians, would need to monitor and track two different versions of the measure for the 2019 reporting year. The commenter requested that the measure modifications for all collection types take effect starting in 2020 to improve measure alignment. Another commenter concurred with CMS that the numerator definition needs to be updated to "clarify that screening for tobacco use and tobacco cessation intervention do not have to occur in the same encounter, but must occur during the 24-month look-back period", but the denominator population (population '2') CMS uses for this measure differs widely from the benchmarked measure definition (the total population). Specifically, the benchmarked denominator includes patients who were not tobacco users, while the new measure (with updated numerator specifications) does not include those patients, thus changing the population and performance rate to a substantial degree. Therefore, the commenter stated that CMS should acknowledge that this is a material change and should classify this measure as pay-for-reporting for ACO and MIPS group submissions until an appropriate benchmark can be established. **Response:** We thank the commenters for supporting the revision to measure Q226. We appreciate the commenters concerns that the measure should be calculated as pay-for-reporting for the 2019 MIPS performance period. The revision to the CMS Web Interface Measure Specifications collection type aligns with the intent of the measure and brings it into alignment with the other collection types. However, due to the mid-year change to the measure specification (as discussed in more detail under section III.E.1.b) we intend to redesignate the CMS Web Interface Measure Specifications collection type for measure Q226 as pay-for-reporting in the Shared Savings Program for performance years starting in 2019 as provided in § 425.502(a)(5). Additionally, we will exclude the measure from MIPS scoring for the 2019 MIPS performance period in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement and the measure was reported through the CMS Web Interface Measure Specifications collection type. Regarding the commenter concerned with the CMS Web Interface Measure Specifications collection type and the eCQM Specifications collection type being out of alignment if this change is finalized, we believe this change brings these two collection types in alignment. The guidance regarding multiple screenings within a performance period "If a patient has multiple tobacco use screenings during the 24-month period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements" will remain within the specification of both collection types. The change to the CMS Web Interface Measure Specifications collection type only impacts the timing of the quality action and not the denominator eligible encounter. This measure underwent a substantive change in 2018 MIPS which revised this measure to have three performance rates rather than one performance rate. At that time, a new benchmark was created since the second performance rate was utilized for benchmark: b. Percentage of patients aged 18 years and older who identified as a tobacco user who received tobacco cessation intervention. Therefore, the benchmark was more focused on the population of patients screened as tobacco users that were provided cessation. The performance rate being utilized for benchmark has not changed between the 2018 and 2019 performance period. After consideration of the comments, we are finalizing the changes to measure Q226 as proposed for the 2019 MIPS performance period/2021 MIPS payment year and future years. We will continue to require this measure for groups, APM Entities, and virtual groups reporting through the CMS Web Interface Measure Specifications collection type. However, we are redesignating it as "pay-for-reporting" in the Shared Savings Program for performance years starting in 2019 as provided in § 425.502(a)(5), and we will exclude the measure from MIPS scoring for the 2019 MIPS performance period in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided it met the data completeness requirement and the measure was reported through the CMS Web Interface Measure Specifications collection type. For further discussion on how this measure will be scored under the Shared Savings Program see section III.E.1.b of this final rule. For further discussion on how this measure will be scored under the MIPS Program Quality Performance Category see section III.K.3.c.(1) of this final rule.	

Appendix 2: Improvement Activities

NOTE: In this final rule, for the CY 2020 performance period and future years, we are finalizing our proposals to: (1) add two new improvement activities; (2) modify seven existing improvement activities; and (3) remove 15 improvement activities from the Inventory. These are discussed in greater detail below.

Table A: New Improvement Activities for the MIPS CY 2020 Performance Period and Future Years

Proposed Improvement Activity	
Proposed Activity ID:	**IA_BE_XX**
Proposed Subcategory:	Beneficiary Engagement
Proposed Activity Title:	Drug Cost Transparency
Proposed Activity Description:	To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s).[1])
Proposed Weighting:	High
Rationale:	The costs of prescription drugs is a driving cost of overall health care spending in the United States and of out-of-pocket health care expenses for patients. As we consider broader efforts to increase transparency for patients, payers, provider organizations, and clinicians, as well as begin to drive down drug prices, this activity serves as a mechanism for drug price transparency at the clinician-patient level and may protect patients from unforeseen costs. By discussing drug pricing with patients, clinicians may better prescribe medications patients can afford, which could have the effect of increasing patient medication compliance and adherence. Thus, we believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, per the improvement activity definition which has been codified at § 414.1305. This activity is weighted as high due to difficulties clinicians may have in identifying drug costs and out-of-pocket costs of drugs for individual patients as costs and reimbursement amounts vary by drug and payer, as well as challenges with identifying the appropriateness of patient assistance programs.[2] [3] As stated previously, we have given certain improvement activities high-weighting due to the intensity of the activity (81 FR 77194). To summarize, we believe that an activity that requires significant investment of time and resources should be high-weighted.
Comments:	Several commenters supported the inclusion of this improvement activity. One commenter stated that many practices provide this type of financial counseling without reimbursement, and this improvement activity would be a way of recognizing eligible clinicians and practices for these services. One commenter stated that in addition to drug costs, the improvement activity should include a screening tool to identify additional barriers to medication adherence for patients. Another commenter stated their support for this activity in that discussing drug costs can help increase patient access to these therapies.

Response:	We appreciate the commenters' support. This improvement activity is meant to incentivize clinicians to provide counseling about drug costs so patients and their caregivers are aware of out-of-pocket costs. We disagree that the improvement activity should include a screening tool to identify additional barriers to medication adherence for patients; it is limited to drug costs in an effort to prioritize drug cost transparency.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_25**
Subcategory:	Beneficiary Engagement
Activity Title:	Drug Cost Transparency
Activity Description:	To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s).[1])
Weighting:	High
Proposed Improvement Activity	
Proposed Activity ID:	**IA_CC_XX**
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes.
Proposed Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician must attest that they reported MACRA patient relationship codes (PRC) using the applicable HCPCS modifiers on 50 percent or more of their Medicare claims for a minimum of a continuous 90-day period within the performance period. Reporting the PRC modifiers enables the identification of a clinician's relationship with, and responsibility for, a patient at the time of furnishing an item or service. See the CY 2018 PFS final rule (82 FR 53232 through 53234) for more details on these codes.
Proposed Weighting:	High
Rationale:	The patient relationship categories and codes define and distinguish the relationship and responsibilities of a clinician with a patient at the point of furnishing an item or service. These codes provide insight into clinician interactions with patients and identify the clinician's relationship to and responsibility for the patient at the time of furnishing an item or service. These codes were developed, as required under section 1848(r)(3) of the Act, to facilitate the attribution of patients and episodes to one or more clinicians. Beginning in 2018, clinicians started voluntarily reporting the patient relationship codes using the applicable HCPCS modifiers (82 FR 53232 through 53234). To properly report the code modifiers, clinicians must add one of the modifiers to each claim line. We proposed that, for the CY 2020 performance period and beyond, clinicians who choose to report the modifiers on 50 percent or more of their Medicare claims for a minimum of a continuous 90-day period within the performance period would earn one (1) high-weighted improvement activity. We believe reporting these modifiers would provide the minimum sample of data necessary to access the modifiers' ability to capture the clinician's relationship with the patient and whether the clinician is appropriately reporting the modifiers. This improvement activity is weighted as high

	due to the intensity of the activity. We believe reporting the modifiers to each claim line for 50 percent or more of Medicare claims continuously for 90 days requires significant investment of time and resources and should be weighted high. For the initial and current period of voluntary reporting the PRC modifiers, where clinicians gain familiarity, data collected will be used to provide aggregate feedback on the performance of clinicians in using the codes within different clinical scenarios and specialties. Data collected from this activity will be used to test the reliability and validity of the modifiers in measuring the clinician's relationship to and responsibility for the Medicare patient before we consider whether to propose in future rulemaking to require the reporting of the PRC modifiers on claims. In the event that we do decide to require such reporting, we would likely propose to remove this improvement activity from MIPS.
Comments:	Several commenters supported the inclusion of this improvement activity. Commenters stated that this would provide us with a better understanding of the types of relationships clinicians have with their patients without imposing a regulatory burden. One commenter stated that increasing the number of eligible clinicians who report patient relationship codes will help to facilitate the creation of meaningful cost measures and alternative payment models. A commenter stated that this improvement activity will be useful for clinicians that are part of large care coordination teams treating patients with complex chronic disease. An additional commenter supported weighting this improvement activity as High due to the significant investment of time and resources required. A commenter suggested that we amend claim forms to allow for more space for PRC modifiers, and recommended considering using HCPCS codes instead of HCPCS modifiers.
Response:	We appreciate the commenters' support. We anticipate this improvement activity will provide clinicians and us with a better understanding of a clinician's relationship with, and responsibility for, a patient at the time of furnishing an item or service. We intend to keep improving clinician and patient relationships by consulting with stakeholders and experts, and through testing and research, to use the proper reporting mechanism for clinician-patient relationships. Before implementing the PRC, we sought stakeholder input which included consulting the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel, which is responsible for maintaining the CPT code set. They recommended CPT Modifiers as the best way to operationalize the reporting of patient relationship codes.[4] We also received public comments indicating that CPT Modifiers would be the best way to operationalize the reporting of patient relationship codes.[5] We plan to continue to improve the reporting of the Patient Relationship Categories and Codes through testing and feedback from stakeholders before possibly incorporating it into cost measures. Depending on the recommendations from the testing, we will consider improving the reporting of the PRC which may include modifying the claim forms through reporting patient relationship through CPT codes. Changes or updates to the improvement activity would be through the notice and comment rulemaking process.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_CC_18**
Subcategory:	Care Coordination
Activity Title:	Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes.
Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician must attest that they reported MACRA patient relationship codes (PRC) using the applicable HCPCS modifiers on 50 percent or more of their Medicare claims for a minimum of a

	continuous 90-day period within the performance period. Reporting the PRC modifiers enables the identification of a clinician's relationship with, and responsibility for, a patient at the time of furnishing an item or service. See the CY 2018 PFS final rule (82 FR 53232 through 53234) for more details on these codes.
Weighting:	High

1/ See the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses, Final Rule, 84 FR 23832, 23883 (May 23, 2019).

2/Allan GM, Lexchin J, Wiebe N. *Physician awareness of drug cost: a systematic review*. PLoS Med. 2007 Sep; 4(9):e283. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/17896856.

3/ Arora V, Moriates C, Shah N. *The challenge of understanding health care costs and charges*. AMA Journal of Ethics. 2015; 17(11): 1046. doi: 10.1001/journalofethics.2015.17.11.stas1-1511.

4/ See CMS Patient Relationship Categories and Codes. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-Relationship-Categories-and-Codes.pdf.

5/ See CMS Patient Relationship Categories and Codes. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-Relationship-Categories-and-Codes.pdf

TABLE B: Changes to Previously Adopted Improvement Activities for the MIPS CY 2020 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_PSPA_28**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Completion of an Accredited Safety or Quality Improvement Program
Current Activity Description:	Completion of an accredited performance improvement continuing medical education program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information.
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain)" as an example of an accredited continuing medical education (CME) program that could meet this improvement activity. Due to the importance of safe prescribing to prevent opioid misuse and opioid use disorder, CME programs related to opioid analgesic REMS may be especially useful to MIPS eligible clinicians in their attempts to prevent opioid misuse among their patients and combat the opioid epidemic.
Proposed Revised Activity Description:	Completion of an accredited performance improvement continuing medical education (CME) program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information. An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain).
Comments:	Several commenters supported the modification of this improvement activity. Two commenters stated that the addition of opioid analgesic REMS is especially important due to the current public health challenges in addressing opioid misuse.
Response:	We appreciate the commenters' support. The modification to this improvement activity provides an additional example that clinicians can use to meet this activity that may improve safe prescribing to prevention opioid misuse and opioid use disorder.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_28**

Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Completion of an Accredited Safety or Quality Improvement Program
Activity Description:	Completion of an accredited performance improvement continuing medical education (CME) program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information. An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain).
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PM_2**
Current Subcategory:	Population Management
Current Activity Title:	Anticoagulant Management Improvements
Current Activity Description:	Individual MIPS eligible clinicians and groups who prescribe oral Vitamin K antagonist therapy (warfarin) must attest that, for 60 percent of practice patients in the transition year and 75 percent of practice patients in Quality Payment Program Year 2 and future years, their ambulatory care patients receiving warfarin are being managed by one or more of the following improvement activities: • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up; and patient communication of results and dosing decisions; and/or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Current Weighting:	High

Proposed Change and Rationale:	Addition of "anti-coagulation medications (oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors)"; and "Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program)." This language was consolidated from IA_PM_1, which was proposed for removal in Table C. We believe IA_PM_1 is duplicative in content to, but less robust than IA_PM_2, with overall fewer examples of actions that can be undertaken to satisfy the intent of the improvement activity. However, IA_PM_1 contained more detail about the type of anti-coagulation medication that could be prescribed to satisfy this activity and an additional example of an action that can be undertaken to satisfy the intent of IA_PM_2, participation in systematic anticoagulation program; so these elements of IA_PM_IA were added to IA_PM_2. Removal of ", for 60 percent of practice patients in the transition year … in Quality Payment Program Year 2 and future years." These time references to transition year and Quality Payment Program Year 2 are now irrelevant because they are in the past. We note that this proposed change was made in conjunction with finalization of the removal of IA_PM_1 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_PM_1.
Proposed Revised Activity Description:	Individual MIPS eligible clinicians and groups who prescribe anti-coagulation medications (including, but not limited to oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors) must attest that for 75 percent of their ambulatory care patients receiving these medications are being managed with support from one or more of the following improvement activities: • Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program); • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the commenters' support. The modifications to this improvement activity allows clinicians to attest to one consolidated improvement activity with five relevant examples. Additionally, the removal of reference to the transition year and Quality Payment Program Year 2 will minimize confusion as those time periods are now in the past.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PM_2**
Subcategory:	Population Management
Activity Title:	Anticoagulant Management Improvements

Activity Description:	Individual MIPS eligible clinicians and groups who prescribe anti-coagulation medications (including, but not limited to oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors) must attest that for 75 percent of their ambulatory care patients receiving these medications are being managed with support from one or more of the following improvement activities: • Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program); • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Weighting:	High
Current Improvement Activity	
Current Activity ID:	**IA_EPA_4**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Additional improvements in access as a result of QIN/QIO TA
Current Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services (for example, investment of on-site diabetes educator).
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "or improve care coordination". We proposed to consolidate this language from activity IA_CC_3, which was proposed for removal in Table C. IA_CC_3 is duplicative to IA_EPA_4 in content related to Quality Innovation Network-Quality Improvement Organization technical assistance, but referred to improving care coordination. We believe the Quality Innovation Network-Quality Improvement Organization technical assistance can support both access to services and care coordination[1] and, furthermore, that care coordination and access to services are inherently related and can logically be combined into one improvement activity. We note that this proposed change was made in conjunction with the removal of IA_CC_3 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_CC_3.
Proposed Revised Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services or improve care coordination (for example, investment of on-site diabetes educator).
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the commenters' support. The modification to this improvement activity allows clinicians to attest to one consolidated improvement activity related to QIN/QIO technical assistance. This modification makes it clear that QIN/QIO activities supports both care coordination and access to services.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_EPA_4**
Subcategory:	Expanded Practice Access

Activity Title:	Additional improvements in access as a result of QIN/QIO TA
Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services or improve care coordination (for example, investment of on-site diabetes educator).
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_19**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes
Current Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following such as: • Multi-Source Feedback; • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data.
Current Weighting:	Medium
Change and Rationale:	Addition of "Bridges to Excellence or American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program". This language was added to consolidate it from IA_PSPA_14, which was proposed for removal in Table C. We believe IA_PSPA_14 is duplicative in content, but less robust than IA_PSPA_19 related to adopting a model for quality improvement. However, IA_PSPA_14 contains a unique relevant example that we wish to preserve under IA_PSPA_19. We note that this proposed change was made in conjunction with the removal of IA_PSPA_14 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_PSPA_14.
Proposed Revised Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following, such as: • Participation in multisource feedback;[2] • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participation in Bridges to Excellence;[3] • Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.[4]
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the commenters' support. The modifications to this improvement activity allows clinicians to attest to one consolidated improvement activity related to formal quality improvement models with nine relevant examples.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	

Activity ID:	**IA_PSPA_19**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes
Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following, such as: • Participation in multisource feedback;[2] • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participation in Bridges to Excellence;[3] • Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.[4]
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_BE_7**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Activity Description:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed the addition of activity description language from four other improvement activities related to participation in QCDR; IA_BE_11 Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan; IA_BE_2 Use of QCDR to support clinical decision making; IA_BE_9 Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement; and IA_BE_10 Participation in a QCDR, that promotes implementation of patient self-action plans. The activity description will include the current (IA_BE_7) activity description with the addition of "Participation in a Qualified Clinical Data Registry and"…, including: • "The use of processes and tools that engage patients for adherence to treatment plans" (from IA_BE_11); • "Activities that promote implementation of shared clinical decision making capabilities" (from IA_BE_2); • "Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" (from IA_BE_9); • "Activities that promote implementation of patient self-action plans" (from IA_BE_10). This language was proposed to consolidate activity description language from improvement activities was proposed for removal in Table C (IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10). The activities proposed for removal are duplicative to IA_BE_7. We also proposed to remove the language "use of…tools" to better capture the content of the consolidated improvement activity regarding promoting patient engagement more broadly.

	We note that this proposed change was made in conjunction with and is contingent upon finalization of the removal of IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10.
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR), that promotes patient engagement, including: • Use of processes and tools that engage patients for adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision making capabilities; or • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Comments:	Several commenters supported the modification of this improvement activity. One commenter recommended increasing the weighting for this improvement activity to High. Another commenter also recommended that this improvement activity be modified to include participation in nationally validated and risk-adjusted clinical data registries.
Response:	We appreciate the commenters' support. The modifications to this improvement activity allow clinicians to attest to one consolidated improvement activity related to participation in a QCDR with four relevant examples of activities related to patient engagement. The modifications do not increase the effort required, and therefore, we do not believe the weighting of the improvement activity should be increased. We refer readers to section III.I.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59776 through 59777) where we discussed that high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. This improvement activity promotes use of QCDRs. If clinicians would like to receive credit for alternative data registries, we suggest considering attesting to another appropriate improvement activity, such as IA_PSPA_14, Participation in Quality Improvement Initiatives or IA_PSPA_19, Implementation of formal quality improvement methods, practice changes, or other practice improvement processes.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_7**
Subcategory:	Beneficiary Engagement
Activity Title:	Participation in a QCDR, that promotes use of patient engagement tools.
Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR), that promotes patient engagement, including: • Use of processes and tools that engage patients for adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision making capabilities; or • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_7**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of QCDR data for ongoing practice assessment and improvements
Current Activity Description:	Use of QCDR data, for ongoing practice assessment and improvements in patient safety.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed the addition of activity description language from four other improvement activities related to participation in QCDR; IA_CC_6 Use of QCDR to promote standard practices, tools and processes in practice for improvement in care coordination; IA_AHE_4 Leveraging a QCDR for use of standard questionnaires;

	IA_AHE_2 Leveraging a QCDR to standardize processes for screening; and IA_PM_10 Use of QCDR data for quality improvement such as comparative analysis reports across patient populations. The activity description will include the current (IA_PSPA_7) activity description with the addition of "Participation in a Qualified Clinical Data Registry and"… including: • "Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups)" (from IA_CC_6); • "Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment)" (from IA_AHE_4); • "Use of standardized processes for screening for social determinants of health such as food security, employment and housing" from (from IA_AHE_2); • "Use of supporting QCDR modules that can be incorporated into the certified EHR technology" (This language adapted from IA_AHE_2 and updated to replace "tools" with "QCDR modules" to add additional specificity to the action that can be taken in the QCDR to promote ongoing practice assessment and patient safety.); or • "Use of QCDR data for quality improvement (such as) comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes" (from IA_PM_10). This language was proposed to consolidate improvement activity description language from activities (IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10) proposed for removal in Table C. The activities we are duplicative to IA_PSPA_7. We note that this proposed change was made in conjunction with and is contingent upon finalization of the removal of IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10.
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire[5], MD Anderson Symptom Inventory[6], and/or SF-12/VR-12 functional health status assessment[7]; • Use of standardized processes for screening for social determinants of health such as food security, employment, and housing; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement such as comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes.
Comments:	Several commenters supported the modification of this improvement activity. One commenter recommended increasing the weighting for this improvement activity to High. A commenter also recommended that this improvement activity be modified to include participation in nationally validated and risk-adjusted clinical data registries.
Response:	We appreciate the commenters' support. The modifications to this improvement activity allows clinicians to attest to one consolidated improvement activity related to participation in a QCDR with five relevant examples of activities related to ongoing practice assessment and improvements in patient safety. The modifications do not

	increase the effort required, and therefore, we do not believe the weighting of the improvement activity should be increased. We refer readers to section III.I.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59776 through 59777) where we discussed that high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. This improvement activity promotes use of QCDRs. If clinicians would like to receive credit for alternative data registries, we suggest considering attesting to another appropriate improvement activity, such as IA_PSPA_14, Participation in Quality Improvement Initiatives or IA_PSPA_19, Implementation of formal quality improvement methods, practice changes, or other practice improvement processes.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_7**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Use of QCDR data for ongoing practice assessment and improvements
Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire[5], MD Anderson Symptom Inventory[6], and/or SF-12/VR-12 functional health status assessment[7]; • Use of standardized processes for screening for social determinants of health such as food security, employment, and housing; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement such as comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_BMH_10**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Completion of Collaborative Care Management Training Program
Current Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available as part of the Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI), available to the public, in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed the removal of the reference to the CMS Transforming Clinical Practice Initiative (TCPI) in the activity description. This initiative ended on September 28, 2019,[9] and therefore, is no longer be applicable to this improvement activity description. The example training program referenced, the APA Collaborative Care Model, continues to be available to the public. The revised activity description only proposes to remove reference to TCPI.
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available to the public[8],

	in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the commenters' support. The removal of reference to the TCPI in this improvement activity description will minimize confusion as that initiative ended on September 28, 2019.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BMH_10**
Subcategory:	Behavioral and Mental Health
Activity Title:	Completion of Collaborative Care Management Training Program
Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available to the public[8], in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Weighting:	Medium

1/ Quality Improvement Organizations. About QIN-QIO. Available at https://qioprogram.org/about/why-cms-has-qios.

2/ Multisource feedback (MSF), or 360-degree employee evaluation, is a questionnaire-based assessment method in which rates are evaluated by peers, patients, and coworkers on key performance behaviors. More information available at https://www.ncbi.nlm.nih.gov/pubmed/12739254.

3/ Bridges to Excellence program. More information available at http://www.bridgestoexcellence.org/.

4/ American Board of Medical Specialties Portfolio Program. More information is available at https://mocportfolioprogram.org/about-us/.

5/ The Seattle Angina Questionnaire is a self-assessed health-related quality of life instrument for coronary artery disease. See: Spertus JA et al. *Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease.* J Am Coll Cardiol. 1995 Feb;25(2):333-41. Available at https://www.ncbi.nlm.nih.gov/pubmed/7829785.

6/ The MD Anderson Symptom Inventory (MDASI) is a multi-symptom patient-reported outcome (PRO) measure for clinical and research use. Available at https://www.mdanderson.org/research/departments-labs-institutes/departments-divisions/symptom-research/symptom-assessment-tools/md-anderson-symptom-inventory.html.

7/ The Optum SF Health Surveys are patient-reported outcome (PRO) surveys across eight health domains. Available at https://www.optum.com/solutions/life-sciences/answer-research/patient-insights/sf-health-surveys.html?s=PPC&pstc=optum:ppc:LS_4.1_2018:g:ls:Frm:18wd1fk01rr23&ppcid=sf12&adid=323753202402&adgroupid=52618954298&campaignid=1036340767&o=optum:ppc:LS_4.1_2018:frm:ls:Frm:18wd1fk01rr23&gclid=Cj0KCQjwg73kBRDVARIsAF-kEH_sDfonepf7U7tsZzzLcHc15b_DxREHpFu0kNGwu2ANu-33WiGoSBIaAgIdEALw_wcB.

8/ The American Psychiatric Association (APA) Collaborative Care Model has been shown to be an effective and efficient model in delivering integrated care. More information on this model and the training program is available at https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/learn.

9/ Transforming Clinical Practice Initiative. Available at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

TABLE C: Improvement Activities for Removal for the MIPS CY 2020 MIPS Performance Period and Future Years

We note that in the CY 2020 PFS proposed rule [84 FR 40765], we inadvertently referenced 14 improvement activities proposed for removal even though there were 15 improvement activities proposed for removal in Table C. We are correcting that typographical error here. In this final rule, we are finalizing our proposals as proposed to remove 15 previously finalized improvement activities from the MIPS Program for the MIPS CY 2020 performance period and future years. These improvement activities are discussed in detail below. Improvement activity removal factors are discussed in section III.K.3.c.(3) of this final rule.

Current Improvement Activity	
Current Activity ID:	**IA_PM_1**
Current Subcategory:	Population Management
Current Activity Title:	Participation in Systematic Anticoagulation Program
Current Activity Description:	Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program) for 60 percent of practice patients in the transition year and 75 percent of practice patients in Quality Payment Program Year 2 and future years, who receive anti-coagulation medications (warfarin or other coagulation cascade inhibitors).
Current Weighting:	High
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PM_2. We proposed consolidating the unique language from IA_PM_1 into IA_PM_2 per the change in Table B. The revised IA_PM_2 adds additional detail from IA_PM_1. We note that this proposed removal was made in conjunction with our decision to modify IA_PM_2 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of this final rule.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PM_2. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PM_2, which we are retaining.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_CC_3**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of additional activity as a result of TA for improving care coordination
Current Activity Description:	Implementation of at least one additional recommended activity from the Quality Innovation Network-Quality Improvement Organization after technical assistance has been provided related to improving care coordination.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of IA_CC_3 under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_EPA_4. We proposed consolidating the unique language from IA_CC_3 into IA_EPA_4 per the change in Table B. The modified language to IA_EPA_4 adds the outcome of "improve care coordination" from the removed activity to make IA_EPA_4 more robust. We note that this proposed removal was made in conjunction with our proposal to modify IA_EPA_4 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of this final rule.

Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_EPA_4. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_EPA_4, which we are retaining.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_14**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in Quality Improvement Initiatives
Current Activity Description:	Participation in other quality improvement programs such as Bridges to Excellence or American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this IA_PSPA_14 under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of the activities included in IA_PSPA_19. We proposed consolidating the unique language in IA_PSPA_14 with IA_PSPA_19 per the change in Table B. The modified language to IA_PSPA_19 adds the examples "Bridges to Excellence" and "American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program" as additional actions that an eligible clinician or group can take to participate in a quality improvement program. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_19 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_19 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_19. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_19, which we are retaining.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_5**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Annual Registration in the Prescription Drug Monitoring Program
Current Activity Description:	Annual registration by eligible clinician or group in the prescription drug monitoring program of the state where they practice. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups must participate for a minimum of 6 months.

Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar in content but less robust than the currently adopted IA_PSPA_6. IA_PSPA_6 requires consultation of and specific thresholds of use for a prescription drug monitoring program instead of simply registering in a prescription drug monitoring program as described in IA_PSPA_5. Because of this, we believe IA_PSPA_6 already captures the essence of IA_PSPA_5 and directly falls into that improvement activity. We note that this proposed removal was made in conjunction with our proposal to adopt removal factors in section III.K.3c.(3) of this final rule.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_6. We understand the concern that removal of improvement activities may limit clinician options but clinicians may attest to IA_PSPA_6, as well as other medium-weight IAs. As explained in section III.I.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59780 through 59781) the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_24**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Initiate CDC Training on Antibiotic Stewardship
Current Activity Description:	Completion of greater than 50 percent of the modules of the Centers for Disease Control and Prevention antibiotic stewardship course. Note: This activity may be selected once every 4 years, to avoid duplicative information given that some of the modules may change on a year by year basis, but over 4 years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is less robust than IA_PSPA_23. IA_PSPA_23 requires completion of all modules of a Centers for Disease Control and Prevention antibiotic stewardship course, instead of 50 percent of modules of a Centers for Disease Control and Prevention antibiotic stewardship course. Because of this, we believe IA_PSPA_23 already captures the essence of IA_PSPA_24 and directly fall into that improvement activity. We note that this proposal was made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of this referenced proposal. We refer readers to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_23. We understand the concern that

	removal of improvement activities may limit clinician options but clinicians may attest to other medium-weight IAs. As explained in section III.I.3.h.(4)(d)(i)(C) of the CY 2019 PFS final rule (83 FR 59780 through 59781) the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BMH_3**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Unhealthy alcohol use
Current Activity Description:	Unhealthy alcohol use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including screening and brief counseling (refer to NQF #2152) for patients with co-occurring conditions of behavioral or mental health conditions.
Current Weighting:	Medium
Removal Rationale:	We proposed removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to the currently adopted IA_BMH_9. We believe IA_BMH_9 is more robust because it requires a threshold of patients for which this unhealthy alcohol use screening must be completed, whereas IA_BMH_3 simply requires engagement, screening and counseling without such a threshold. Because of this, we believe IA_BMH_9 already captures the essence of IA_BMH_3 and directly fall into that improvement activity. We note that this proposal was made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of this referenced proposal. We refer readers to section III.K.3.c.(3) in this final rule where we are finalizing our proposals to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BMH_9. We understand the concern that removal of improvement activities may limit clinician options but clinicians may attest to other medium-weight IAs. As explained in section III.I.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59780 through 59781) the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BE_11**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan
Current Activity Description:	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.
Current Weighting:	Medium

Removal Rationale:	We proposed removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we proposed changes to IA_BE_7 that add "…the use of processes and tools that engage patients for adherence to treatment plan" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the changes to IA_BE_7 capture the essence of IA_BE_11. We note that this proposed removal was made in conjunction with our proposal to modify IA_BE_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_BE_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BE_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_BE_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BE_2**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of QCDR to support clinical decision making
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposed changes to IA_BE_7 that add "activities that promote implementation of shared clinical decision making capabilities" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the changes to IA_BE_7 capture the essence of IA_BE_2. We note that this proposed removal was made in conjunction with our proposal to modify IA_BE_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_BE_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.

Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BE_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_BE_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BE_9**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of QCDR patient experience data to inform and advance improvements in beneficiary
Current Activity Description:	Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we proposed changes to IA_BE_7 that add "use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the changes to IA_BE_7 capture the essence of IA_BE_9. We note that this proposed removal was made in conjunction with our proposal to modify IA_BE_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765).Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to sections Table B of this final rule where we are finalizing our proposal to modify IA_BE_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BE_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_BE_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BE_10**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes implementation of patient self-action plans.
Current Activity Description:	Participation in a QCDR, that promotes implementation of patient self-action plans.

Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we proposed changes to IA_BE_7 to add "[activities that] promote implementation of patient self-action plans" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the changes to IA_BE_7 capture the essence of IA_BE_10. We note that this proposed removal was made in conjunction with our proposal to modify IA_BE_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_BE_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BE_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_BE_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_CC_6**
Current Subcategory:	Care Coordination
Current Activity Title:	Use of QCDR to promote standard practices, tools and processes in practice for improvement in care coordination
Current Activity Description:	Participation in a Qualified Clinical Data Registry, demonstrating performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups).
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we proposed changes to IA_PSPA_7 to add "performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups);" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_CC_6. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal adopt removal factors.

Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_AHE_4**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Leveraging a QCDR for use of standard questionnaires
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities for use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment).
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we proposed changes to IA_PSPA_7 to add "use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment);" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_AHE_4. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765).Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.

Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_AHE_2**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Leveraging a QCDR to standardize processes for screening
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities for use of standardized processes for screening for social determinants of health such as food security, employment and housing. Use of supporting tools that can be incorporated into the certified EHR technology is also suggested.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we proposed changes to IA_PSPA_7 to add "use of standardized processes for screening for social determinants of health such as food security, employment and housing…use of supporting tools that can be incorporated into the certified EHR technology" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_AHE_2. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765).Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to sections Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PM_10**
Current Subcategory:	Population Management
Current Activity Title:	Use of QCDR data for quality improvement such as comparative analysis reports across patient populations
Current Activity Description:	Participation in a QCDR, clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as a hospital or medical or surgical society. Activity must include use of QCDR data for quality improvement (for example, comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome).
Current Weighting:	Medium

Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we proposed changes to IA_PSPA_7 to add "use of QCDR data for quality improvement such as comparative analysis reports across patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_PM_10. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765).Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_CC_4**
Current Subcategory:	Care Coordination
Current Activity Title:	TCPI Participation
Current Activity Description:	Participation in CMS Transforming Clinical Practice Initiative
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 7, improvement activity is obsolete. The Transforming Clinical Practice Initiative ended on September 28, 2019[1] and therefore, clinicians are no longer be able to attest to this improvement activity. We note that this proposed removal was made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of this proposal. We refer readers to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. Since it is no longer feasible for clinicians to attest to this improvement activity due to the TCPI ending on September 28, 2019, we do not believe removal of this improvement activity would limit clinician options.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.

Finalized Improvement Activity	
Activity ID:	N/A – Removed

1/ Transforming Clinical Practice Initiative. Available at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

Appendix 2: Improvement Activities

NOTE: In this final rule, for the CY 2020 performance period and future years, we are finalizing our proposals to: (1) add two new improvement activities; (2) modify seven existing improvement activities; and (3) remove 15 improvement activities from the Inventory. These are discussed in greater detail below.

Table A: New Improvement Activities for the MIPS CY 2020 Performance Period and Future Years

Proposed Improvement Activity	
Proposed Activity ID:	**IA_BE_XX**
Proposed Subcategory:	Beneficiary Engagement
Proposed Activity Title:	Drug Cost Transparency
Proposed Activity Description:	To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s).[1])
Proposed Weighting:	High
Rationale:	The costs of prescription drugs is a driving cost of overall health care spending in the United States and of out-of-pocket health care expenses for patients. As we consider broader efforts to increase transparency for patients, payers, provider organizations, and clinicians, as well as begin to drive down drug prices, this activity serves as a mechanism for drug price transparency at the clinician-patient level and may protect patients from unforeseen costs. By discussing drug pricing with patients, clinicians may better prescribe medications patients can afford, which could have the effect of increasing patient medication compliance and adherence. Thus, we believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, per the improvement activity definition which has been codified at § 414.1305. This activity is weighted as high due to difficulties clinicians may have in identifying drug costs and out-of-pocket costs of drugs for individual patients as costs and reimbursement amounts vary by drug and payer, as well as challenges with identifying the appropriateness of patient assistance programs.[2] [3] As stated previously, we have given certain improvement activities high-weighting due to the intensity of the activity (81 FR 77194). To summarize, we believe that an activity that requires significant investment of time and resources should be high-weighted.
Comments:	Several commenters supported the inclusion of this improvement activity. One commenter stated that many practices provide this type of financial counseling without reimbursement, and this improvement activity would be a way of recognizing eligible clinicians and practices for these services. One commenter stated that in addition to drug costs, the improvement activity should include a screening tool to identify additional barriers to medication adherence for patients. Another commenter stated their support for this activity in that discussing drug costs can help increase patient access to these therapies.

Response:	We appreciate the commenters' support. This improvement activity is meant to incentivize clinicians to provide counseling about drug costs so patients and their caregivers are aware of out-of-pocket costs. We disagree that the improvement activity should include a screening tool to identify additional barriers to medication adherence for patients; it is limited to drug costs in an effort to prioritize drug cost transparency.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_25**
Subcategory:	Beneficiary Engagement
Activity Title:	Drug Cost Transparency
Activity Description:	To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s).[1])
Weighting:	High
Proposed Improvement Activity	
Proposed Activity ID:	**IA_CC_XX**
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes.
Proposed Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician must attest that they reported MACRA patient relationship codes (PRC) using the applicable HCPCS modifiers on 50 percent or more of their Medicare claims for a minimum of a continuous 90-day period within the performance period. Reporting the PRC modifiers enables the identification of a clinician's relationship with, and responsibility for, a patient at the time of furnishing an item or service. See the CY 2018 PFS final rule (82 FR 53232 through 53234) for more details on these codes.
Proposed Weighting:	High
Rationale:	The patient relationship categories and codes define and distinguish the relationship and responsibilities of a clinician with a patient at the point of furnishing an item or service. These codes provide insight into clinician interactions with patients and identify the clinician's relationship to and responsibility for the patient at the time of furnishing an item or service. These codes were developed, as required under section 1848(r)(3) of the Act, to facilitate the attribution of patients and episodes to one or more clinicians. Beginning in 2018, clinicians started voluntarily reporting the patient relationship codes using the applicable HCPCS modifiers (82 FR 53232 through 53234). To properly report the code modifiers, clinicians must add one of the modifiers to each claim line. We proposed that, for the CY 2020 performance period and beyond, clinicians who choose to report the modifiers on 50 percent or more of their Medicare claims for a minimum of a continuous 90-day period within the performance period would earn one (1) high-weighted improvement activity. We believe reporting these modifiers would provide the minimum sample of data necessary to access the modifiers' ability to capture the clinician's relationship with the patient and whether the clinician is appropriately reporting the modifiers. This improvement activity is weighted as high

	due to the intensity of the activity. We believe reporting the modifiers to each claim line for 50 percent or more of Medicare claims continuously for 90 days requires significant investment of time and resources and should be weighted high. For the initial and current period of voluntary reporting the PRC modifiers, where clinicians gain familiarity, data collected will be used to provide aggregate feedback on the performance of clinicians in using the codes within different clinical scenarios and specialties. Data collected from this activity will be used to test the reliability and validity of the modifiers in measuring the clinician's relationship to and responsibility for the Medicare patient before we consider whether to propose in future rulemaking to require the reporting of the PRC modifiers on claims. In the event that we do decide to require such reporting, we would likely propose to remove this improvement activity from MIPS.
Comments:	Several commenters supported the inclusion of this improvement activity. Commenters stated that this would provide us with a better understanding of the types of relationships clinicians have with their patients without imposing a regulatory burden. One commenter stated that increasing the number of eligible clinicians who report patient relationship codes will help to facilitate the creation of meaningful cost measures and alternative payment models. A commenter stated that this improvement activity will be useful for clinicians that are part of large care coordination teams treating patients with complex chronic disease. An additional commenter supported weighting this improvement activity as High due to the significant investment of time and resources required. A commenter suggested that we amend claim forms to allow for more space for PRC modifiers, and recommended considering using HCPCS codes instead of HCPCS modifiers.
Response:	We appreciate the commenters' support. We anticipate this improvement activity will provide clinicians and us with a better understanding of a clinician's relationship with, and responsibility for, a patient at the time of furnishing an item or service. We intend to keep improving clinician and patient relationships by consulting with stakeholders and experts, and through testing and research, to use the proper reporting mechanism for clinician-patient relationships. Before implementing the PRC, we sought stakeholder input which included consulting the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel, which is responsible for maintaining the CPT code set. They recommended CPT Modifiers as the best way to operationalize the reporting of patient relationship codes.[4] We also received public comments indicating that CPT Modifiers would be the best way to operationalize the reporting of patient relationship codes.[5] We plan to continue to improve the reporting of the Patient Relationship Categories and Codes through testing and feedback from stakeholders before possibly incorporating it into cost measures. Depending on the recommendations from the testing, we will consider improving the reporting of the PRC which may include modifying the claim forms through reporting patient relationship through CPT codes. Changes or updates to the improvement activity would be through the notice and comment rulemaking process.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_CC_18**
Subcategory:	Care Coordination
Activity Title:	Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes.
Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician must attest that they reported MACRA patient relationship codes (PRC) using the applicable HCPCS modifiers on 50 percent or more of their Medicare claims for a minimum of a

	continuous 90-day period within the performance period. Reporting the PRC modifiers enables the identification of a clinician's relationship with, and responsibility for, a patient at the time of furnishing an item or service. See the CY 2018 PFS final rule (82 FR 53232 through 53234) for more details on these codes.
Weighting:	High

1/ See the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses, Final Rule, 84 FR 23832, 23883 (May 23, 2019).

2/Allan GM, Lexchin J, Wiebe N. *Physician awareness of drug cost: a systematic review*. PLoS Med. 2007 Sep; 4(9):e283. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/17896856.

3/ Arora V, Moriates C, Shah N. *The challenge of understanding health care costs and charges*. AMA Journal of Ethics. 2015; 17(11): 1046. doi: 10.1001/journalofethics.2015.17.11.stas1-1511.

4/ See CMS Patient Relationship Categories and Codes. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-Relationship-Categories-and-Codes.pdf.

5/ See CMS Patient Relationship Categories and Codes. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-Relationship-Categories-and-Codes.pdf

TABLE B: Changes to Previously Adopted Improvement Activities for the MIPS CY 2020 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_PSPA_28**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Completion of an Accredited Safety or Quality Improvement Program
Current Activity Description:	Completion of an accredited performance improvement continuing medical education program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information.
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain)" as an example of an accredited continuing medical education (CME) program that could meet this improvement activity. Due to the importance of safe prescribing to prevent opioid misuse and opioid use disorder, CME programs related to opioid analgesic REMS may be especially useful to MIPS eligible clinicians in their attempts to prevent opioid misuse among their patients and combat the opioid epidemic.
Proposed Revised Activity Description:	Completion of an accredited performance improvement continuing medical education (CME) program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information. An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain).
Comments:	Several commenters supported the modification of this improvement activity. Two commenters stated that the addition of opioid analgesic REMS is especially important due to the current public health challenges in addressing opioid misuse.
Response:	We appreciate the commenters' support. The modification to this improvement activity provides an additional example that clinicians can use to meet this activity that may improve safe prescribing to prevention opioid misuse and opioid use disorder.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_28**

Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Completion of an Accredited Safety or Quality Improvement Program
Activity Description:	Completion of an accredited performance improvement continuing medical education (CME) program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information. An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain).
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PM_2**
Current Subcategory:	Population Management
Current Activity Title:	Anticoagulant Management Improvements
Current Activity Description:	Individual MIPS eligible clinicians and groups who prescribe oral Vitamin K antagonist therapy (warfarin) must attest that, for 60 percent of practice patients in the transition year and 75 percent of practice patients in Quality Payment Program Year 2 and future years, their ambulatory care patients receiving warfarin are being managed by one or more of the following improvement activities: • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up; and patient communication of results and dosing decisions; and/or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Current Weighting:	High

Proposed Change and Rationale:	Addition of "anti-coagulation medications (oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors)"; and "Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program)." This language was consolidated from IA_PM_1, which was proposed for removal in Table C. We believe IA_PM_1 is duplicative in content to, but less robust than IA_PM_2, with overall fewer examples of actions that can be undertaken to satisfy the intent of the improvement activity. However, IA_PM_1 contained more detail about the type of anti-coagulation medication that could be prescribed to satisfy this activity and an additional example of an action that can be undertaken to satisfy the intent of IA_PM_2, participation in systematic anticoagulation program; so these elements of IA_PM_IA were added to IA_PM_2. Removal of ", for 60 percent of practice patients in the transition year … in Quality Payment Program Year 2 and future years." These time references to transition year and Quality Payment Program Year 2 are now irrelevant because they are in the past. We note that this proposed change was made in conjunction with finalization of the removal of IA_PM_1 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_PM_1.
Proposed Revised Activity Description:	Individual MIPS eligible clinicians and groups who prescribe anti-coagulation medications (including, but not limited to oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors) must attest that for 75 percent of their ambulatory care patients receiving these medications are being managed with support from one or more of the following improvement activities: • Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program); • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the commenters' support. The modifications to this improvement activity allows clinicians to attest to one consolidated improvement activity with five relevant examples. Additionally, the removal of reference to the transition year and Quality Payment Program Year 2 will minimize confusion as those time periods are now in the past.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PM_2**
Subcategory:	Population Management
Activity Title:	Anticoagulant Management Improvements

Activity Description:	Individual MIPS eligible clinicians and groups who prescribe anti-coagulation medications (including, but not limited to oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors) must attest that for 75 percent of their ambulatory care patients receiving these medications are being managed with support from one or more of the following improvement activities: • Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program); • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Weighting:	High
Current Improvement Activity	
Current Activity ID:	**IA_EPA_4**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Additional improvements in access as a result of QIN/QIO TA
Current Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services (for example, investment of on-site diabetes educator).
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "or improve care coordination". We proposed to consolidate this language from activity IA_CC_3, which was proposed for removal in Table C. IA_CC_3 is duplicative to IA_EPA_4 in content related to Quality Innovation Network-Quality Improvement Organization technical assistance, but referred to improving care coordination. We believe the Quality Innovation Network-Quality Improvement Organization technical assistance can support both access to services and care coordination[1] and, furthermore, that care coordination and access to services are inherently related and can logically be combined into one improvement activity. We note that this proposed change was made in conjunction with the removal of IA_CC_3 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_CC_3.
Proposed Revised Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services or improve care coordination (for example, investment of on-site diabetes educator).
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the commenters' support. The modification to this improvement activity allows clinicians to attest to one consolidated improvement activity related to QIN/QIO technical assistance. This modification makes it clear that QIN/QIO activities supports both care coordination and access to services.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_EPA_4**
Subcategory:	Expanded Practice Access

Activity Title:	Additional improvements in access as a result of QIN/QIO TA
Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services or improve care coordination (for example, investment of on-site diabetes educator).
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_19**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes
Current Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following such as: • Multi-Source Feedback; • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data.
Current Weighting:	Medium
Change and Rationale:	Addition of "Bridges to Excellence or American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program". This language was added to consolidate it from IA_PSPA_14, which was proposed for removal in Table C. We believe IA_PSPA_14 is duplicative in content, but less robust than IA_PSPA_19 related to adopting a model for quality improvement. However, IA_PSPA_14 contains a unique relevant example that we wish to preserve under IA_PSPA_19. We note that this proposed change was made in conjunction with the removal of IA_PSPA_14 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_PSPA_14.
Proposed Revised Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following, such as: • Participation in multisource feedback;[2] • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participation in Bridges to Excellence;[3] • Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.[4]
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the commenters' support. The modifications to this improvement activity allows clinicians to attest to one consolidated improvement activity related to formal quality improvement models with nine relevant examples.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	

Activity ID:	**IA_PSPA_19**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes
Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following, such as: • Participation in multisource feedback;[2] • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participation in Bridges to Excellence;[3] • Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.[4]
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_BE_7**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Activity Description:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed the addition of activity description language from four other improvement activities related to participation in QCDR; IA_BE_11 Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan; IA_BE_2 Use of QCDR to support clinical decision making; IA_BE_9 Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement; and IA_BE_10 Participation in a QCDR, that promotes implementation of patient self-action plans. The activity description will include the current (IA_BE_7) activity description with the addition of "Participation in a Qualified Clinical Data Registry and"…, including: • "The use of processes and tools that engage patients for adherence to treatment plans" (from IA_BE_11); • "Activities that promote implementation of shared clinical decision making capabilities" (from IA_BE_2); • "Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" (from IA_BE_9); • "Activities that promote implementation of patient self-action plans" (from IA_BE_10). This language was proposed to consolidate activity description language from improvement activities was proposed for removal in Table C (IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10). The activities proposed for removal are duplicative to IA_BE_7. We also proposed to remove the language "use of…tools" to better capture the content of the consolidated improvement activity regarding promoting patient engagement more broadly.

	We note that this proposed change was made in conjunction with and is contingent upon finalization of the removal of IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10.
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR), that promotes patient engagement, including: • Use of processes and tools that engage patients for adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision making capabilities; or • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Comments:	Several commenters supported the modification of this improvement activity. One commenter recommended increasing the weighting for this improvement activity to High. Another commenter also recommended that this improvement activity be modified to include participation in nationally validated and risk-adjusted clinical data registries.
Response:	We appreciate the commenters' support. The modifications to this improvement activity allow clinicians to attest to one consolidated improvement activity related to participation in a QCDR with four relevant examples of activities related to patient engagement. The modifications do not increase the effort required, and therefore, we do not believe the weighting of the improvement activity should be increased. We refer readers to section III.I.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59776 through 59777) where we discussed that high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. This improvement activity promotes use of QCDRs. If clinicians would like to receive credit for alternative data registries, we suggest considering attesting to another appropriate improvement activity, such as IA_PSPA_14, Participation in Quality Improvement Initiatives or IA_PSPA_19, Implementation of formal quality improvement methods, practice changes, or other practice improvement processes.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_7**
Subcategory:	Beneficiary Engagement
Activity Title:	Participation in a QCDR, that promotes use of patient engagement tools.
Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR), that promotes patient engagement, including: • Use of processes and tools that engage patients for adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision making capabilities; or • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_7**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of QCDR data for ongoing practice assessment and improvements
Current Activity Description:	Use of QCDR data, for ongoing practice assessment and improvements in patient safety.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed the addition of activity description language from four other improvement activities related to participation in QCDR; IA_CC_6 Use of QCDR to promote standard practices, tools and processes in practice for improvement in care coordination; IA_AHE_4 Leveraging a QCDR for use of standard questionnaires;

	IA_AHE_2 Leveraging a QCDR to standardize processes for screening; and IA_PM_10 Use of QCDR data for quality improvement such as comparative analysis reports across patient populations. The activity description will include the current (IA_PSPA_7) activity description with the addition of "Participation in a Qualified Clinical Data Registry and"… including: • "Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups)" (from IA_CC_6); • "Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment)" (from IA_AHE_4); • "Use of standardized processes for screening for social determinants of health such as food security, employment and housing" from (from IA_AHE_2); • "Use of supporting QCDR modules that can be incorporated into the certified EHR technology" (This language adapted from IA_AHE_2 and updated to replace "tools" with "QCDR modules" to add additional specificity to the action that can be taken in the QCDR to promote ongoing practice assessment and patient safety.); or • "Use of QCDR data for quality improvement (such as) comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes" (from IA_PM_10). This language was proposed to consolidate improvement activity description language from activities (IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10) proposed for removal in Table C. The activities we are duplicative to IA_PSPA_7. We note that this proposed change was made in conjunction with and is contingent upon finalization of the removal of IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10 as discussed in Table C. We refer readers to Table C where we are finalizing the removal of IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10.
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire[5], MD Anderson Symptom Inventory[6], and/or SF-12/VR-12 functional health status assessment[7]; • Use of standardized processes for screening for social determinants of health such as food security, employment, and housing; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement such as comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes.
Comments:	Several commenters supported the modification of this improvement activity. One commenter recommended increasing the weighting for this improvement activity to High. A commenter also recommended that this improvement activity be modified to include participation in nationally validated and risk-adjusted clinical data registries.
Response:	We appreciate the commenters' support. The modifications to this improvement activity allows clinicians to attest to one consolidated improvement activity related to participation in a QCDR with five relevant examples of activities related to ongoing practice assessment and improvements in patient safety. The modifications do not

	increase the effort required, and therefore, we do not believe the weighting of the improvement activity should be increased. We refer readers to section III.I.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59776 through 59777) where we discussed that high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. This improvement activity promotes use of QCDRs. If clinicians would like to receive credit for alternative data registries, we suggest considering attesting to another appropriate improvement activity, such as IA_PSPA_14, Participation in Quality Improvement Initiatives or IA_PSPA_19, Implementation of formal quality improvement methods, practice changes, or other practice improvement processes.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_7**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Use of QCDR data for ongoing practice assessment and improvements
Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire[5], MD Anderson Symptom Inventory[6], and/or SF-12/VR-12 functional health status assessment[7]; • Use of standardized processes for screening for social determinants of health such as food security, employment, and housing; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement such as comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_BMH_10**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Completion of Collaborative Care Management Training Program
Current Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available as part of the Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI), available to the public, in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed the removal of the reference to the CMS Transforming Clinical Practice Initiative (TCPI) in the activity description. This initiative ended on September 28, 2019,[9] and therefore, is no longer be applicable to this improvement activity description. The example training program referenced, the APA Collaborative Care Model, continues to be available to the public. The revised activity description only proposes to remove reference to TCPI.
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available to the public[8],

	in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the commenters' support. The removal of reference to the TCPI in this improvement activity description will minimize confusion as that initiative ended on September 28, 2019.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BMH_10**
Subcategory:	Behavioral and Mental Health
Activity Title:	Completion of Collaborative Care Management Training Program
Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available to the public[8], in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Weighting:	Medium

1/ Quality Improvement Organizations. About QIN-QIO. Available at https://qioprogram.org/about/why-cms-has-qios.

2/ Multisource feedback (MSF), or 360-degree employee evaluation, is a questionnaire-based assessment method in which rates are evaluated by peers, patients, and coworkers on key performance behaviors. More information available at https://www.ncbi.nlm.nih.gov/pubmed/12739254.

3/ Bridges to Excellence program. More information available at http://www.bridgestoexcellence.org/.

4/ American Board of Medical Specialties Portfolio Program. More information is available at https://mocportfolioprogram.org/about-us/.

5/ The Seattle Angina Questionnaire is a self-assessed health-related quality of life instrument for coronary artery disease. See: Spertus JA et al. *Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease.* J Am Coll Cardiol. 1995 Feb;25(2):333-41. Available at https://www.ncbi.nlm.nih.gov/pubmed/7829785.

6/ The MD Anderson Symptom Inventory (MDASI) is a multi-symptom patient-reported outcome (PRO) measure for clinical and research use. Available at https://www.mdanderson.org/research/departments-labs-institutes/departments-divisions/symptom-research/symptom-assessment-tools/md-anderson-symptom-inventory.html.

7/ The Optum SF Health Surveys are patient-reported outcome (PRO) surveys across eight health domains. Available at https://www.optum.com/solutions/life-sciences/answer-research/patient-insights/sf-health-surveys.html?s=PPC&pstc=optum:ppc:LS_4.1_2018:g:ls:Frm:18wd1fk01rr23&ppcid=sf12&adid=323753202402&adgroupid=52618954298&campaignid=1036340767&o=optum:ppc:LS_4.1_2018:frm:ls:Frm:18wd1fk01rr23&gclid=Cj0KCQjwg73kBRDVARIsAF-kEH_sDfonepf7U7tsZzzLcHc15b_DxREHpFu0kNGwu2ANu-33WiGoSBIaAgIdEALw_wcB.

8/ The American Psychiatric Association (APA) Collaborative Care Model has been shown to be an effective and efficient model in delivering integrated care. More information on this model and the training program is available at https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/learn.

9/ Transforming Clinical Practice Initiative. Available at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

TABLE C: Improvement Activities for Removal for the MIPS CY 2020 MIPS Performance Period and Future Years

We note that in the CY 2020 PFS proposed rule [84 FR 40765], we inadvertently referenced 14 improvement activities proposed for removal even though there were 15 improvement activities proposed for removal in Table C. We are correcting that typographical error here. In this final rule, we are finalizing our proposals as proposed to remove 15 previously finalized improvement activities from the MIPS Program for the MIPS CY 2020 performance period and future years. These improvement activities are discussed in detail below. Improvement activity removal factors are discussed in section III.K.3.c.(3) of this final rule.

Current Improvement Activity	
Current Activity ID:	**IA_PM_1**
Current Subcategory:	Population Management
Current Activity Title:	Participation in Systematic Anticoagulation Program
Current Activity Description:	Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program) for 60 percent of practice patients in the transition year and 75 percent of practice patients in Quality Payment Program Year 2 and future years, who receive anti-coagulation medications (warfarin or other coagulation cascade inhibitors).
Current Weighting:	High
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PM_2. We proposed consolidating the unique language from IA_PM_1 into IA_PM_2 per the change in Table B. The revised IA_PM_2 adds additional detail from IA_PM_1. We note that this proposed removal was made in conjunction with our decision to modify IA_PM_2 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of this final rule.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PM_2. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PM_2, which we are retaining.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_CC_3**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of additional activity as a result of TA for improving care coordination
Current Activity Description:	Implementation of at least one additional recommended activity from the Quality Innovation Network-Quality Improvement Organization after technical assistance has been provided related to improving care coordination.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of IA_CC_3 under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_EPA_4. We proposed consolidating the unique language from IA_CC_3 into IA_EPA_4 per the change in Table B. The modified language to IA_EPA_4 adds the outcome of "improve care coordination" from the removed activity to make IA_EPA_4 more robust. We note that this proposed removal was made in conjunction with our proposal to modify IA_EPA_4 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of this final rule.

Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_EPA_4. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_EPA_4, which we are retaining.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_14**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in Quality Improvement Initiatives
Current Activity Description:	Participation in other quality improvement programs such as Bridges to Excellence or American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this IA_PSPA_14 under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of the activities included in IA_PSPA_19. We proposed consolidating the unique language in IA_PSPA_14 with IA_PSPA_19 per the change in Table B. The modified language to IA_PSPA_19 adds the examples "Bridges to Excellence" and "American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program" as additional actions that an eligible clinician or group can take to participate in a quality improvement program. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_19 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_19 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_19. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_19, which we are retaining.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_5**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Annual Registration in the Prescription Drug Monitoring Program
Current Activity Description:	Annual registration by eligible clinician or group in the prescription drug monitoring program of the state where they practice. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups must participate for a minimum of 6 months.

Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar in content but less robust than the currently adopted IA_PSPA_6. IA_PSPA_6 requires consultation of and specific thresholds of use for a prescription drug monitoring program instead of simply registering in a prescription drug monitoring program as described in IA_PSPA_5. Because of this, we believe IA_PSPA_6 already captures the essence of IA_PSPA_5 and directly falls into that improvement activity. We note that this proposed removal was made in conjunction with our proposal to adopt removal factors in section III.K.3c.(3) of this final rule.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_6. We understand the concern that removal of improvement activities may limit clinician options but clinicians may attest to IA_PSPA_6, as well as other medium-weight IAs. As explained in section III.I.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59780 through 59781) the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_24**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Initiate CDC Training on Antibiotic Stewardship
Current Activity Description:	Completion of greater than 50 percent of the modules of the Centers for Disease Control and Prevention antibiotic stewardship course. Note: This activity may be selected once every 4 years, to avoid duplicative information given that some of the modules may change on a year by year basis, but over 4 years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is less robust than IA_PSPA_23. IA_PSPA_23 requires completion of all modules of a Centers for Disease Control and Prevention antibiotic stewardship course, instead of 50 percent of modules of a Centers for Disease Control and Prevention antibiotic stewardship course. Because of this, we believe IA_PSPA_23 already captures the essence of IA_PSPA_24 and directly fall into that improvement activity. We note that this proposal was made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of this referenced proposal. We refer readers to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_23. We understand the concern that

	removal of improvement activities may limit clinician options but clinicians may attest to other medium-weight IAs. As explained in section III.I.3.h.(4)(d)(i)(C) of the CY 2019 PFS final rule (83 FR 59780 through 59781) the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BMH_3**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Unhealthy alcohol use
Current Activity Description:	Unhealthy alcohol use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including screening and brief counseling (refer to NQF #2152) for patients with co-occurring conditions of behavioral or mental health conditions.
Current Weighting:	Medium
Removal Rationale:	We proposed removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to the currently adopted IA_BMH_9. We believe IA_BMH_9 is more robust because it requires a threshold of patients for which this unhealthy alcohol use screening must be completed, whereas IA_BMH_3 simply requires engagement, screening and counseling without such a threshold. Because of this, we believe IA_BMH_9 already captures the essence of IA_BMH_3 and directly fall into that improvement activity. We note that this proposal was made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of this referenced proposal. We refer readers to section III.K.3.c.(3) in this final rule where we are finalizing our proposals to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BMH_9. We understand the concern that removal of improvement activities may limit clinician options but clinicians may attest to other medium-weight IAs. As explained in section III.I.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59780 through 59781) the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BE_11**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan
Current Activity Description:	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.
Current Weighting:	Medium

Removal Rationale:	We proposed removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we proposed changes to IA_BE_7 that add "…the use of processes and tools that engage patients for adherence to treatment plan" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the changes to IA_BE_7 capture the essence of IA_BE_11. We note that this proposed removal was made in conjunction with our proposal to modify IA_BE_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_BE_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BE_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_BE_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BE_2**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of QCDR to support clinical decision making
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposed changes to IA_BE_7 that add "activities that promote implementation of shared clinical decision making capabilities" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the changes to IA_BE_7 capture the essence of IA_BE_2. We note that this proposed removal was made in conjunction with our proposal to modify IA_BE_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_BE_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.

Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BE_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_BE_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BE_9**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of QCDR patient experience data to inform and advance improvements in beneficiary
Current Activity Description:	Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we proposed changes to IA_BE_7 that add "use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the changes to IA_BE_7 capture the essence of IA_BE_9. We note that this proposed removal was made in conjunction with our proposal to modify IA_BE_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765).Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to sections Table B of this final rule where we are finalizing our proposal to modify IA_BE_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BE_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_BE_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_BE_10**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes implementation of patient self-action plans.
Current Activity Description:	Participation in a QCDR, that promotes implementation of patient self-action plans.

Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we proposed changes to IA_BE_7 to add "[activities that] promote implementation of patient self-action plans" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the changes to IA_BE_7 capture the essence of IA_BE_10. We note that this proposed removal was made in conjunction with our proposal to modify IA_BE_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_BE_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_BE_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_BE_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_CC_6**
Current Subcategory:	Care Coordination
Current Activity Title:	Use of QCDR to promote standard practices, tools and processes in practice for improvement in care coordination
Current Activity Description:	Participation in a Qualified Clinical Data Registry, demonstrating performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups).
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we proposed changes to IA_PSPA_7 to add "performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups);" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_CC_6. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal adopt removal factors.

Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_AHE_4**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Leveraging a QCDR for use of standard questionnaires
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities for use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment).
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we proposed changes to IA_PSPA_7 to add "use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment);" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_AHE_4. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765).Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.

Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_AHE_2**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Leveraging a QCDR to standardize processes for screening
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities for use of standardized processes for screening for social determinants of health such as food security, employment and housing. Use of supporting tools that can be incorporated into the certified EHR technology is also suggested.
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we proposed changes to IA_PSPA_7 to add "use of standardized processes for screening for social determinants of health such as food security, employment and housing…use of supporting tools that can be incorporated into the certified EHR technology" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_AHE_2. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765).Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to sections Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PM_10**
Current Subcategory:	Population Management
Current Activity Title:	Use of QCDR data for quality improvement such as comparative analysis reports across patient populations
Current Activity Description:	Participation in a QCDR, clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as a hospital or medical or surgical society. Activity must include use of QCDR data for quality improvement (for example, comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome).
Current Weighting:	Medium

Removal Rationale:	We proposed the removal of this activity under removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we proposed changes to IA_PSPA_7 to add "use of QCDR data for quality improvement such as comparative analysis reports across patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the changes to IA_PSPA_7 capture the essence of IA_PM_10. We note that this proposed removal was made in conjunction with our proposal to modify IA_PSPA_7 in Table B, as well as our proposals to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765).Therefore, this removal is contingent upon finalization of both referenced proposals. We refer readers to Table B of this final rule where we are finalizing our proposal to modify IA_PSPA_7 and to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice. One commenter did not oppose this removal, but expressed concern that removal of multiple QCDR-related improvement activities could lower participation in QCDRs.
Response:	We appreciate the commenters' support. We appreciate the commenters' support. We are removing this improvement activity because we believe it is "duplicative" of IA_PSPA_7. While we understand the concern that removal of improvement activities may limit clinician options, we do not believe removing this activity will limit options as it has the same components as IA_PSPA_7, which we are retaining. We do not believe removal of this improvement activity would lower participation in QCDRs, because there are still four other QCDR-related improvement activities in the Inventory.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_CC_4**
Current Subcategory:	Care Coordination
Current Activity Title:	TCPI Participation
Current Activity Description:	Participation in CMS Transforming Clinical Practice Initiative
Current Weighting:	Medium
Removal Rationale:	We proposed the removal of this activity under removal factor 7, improvement activity is obsolete. The Transforming Clinical Practice Initiative ended on September 28, 2019[1] and therefore, clinicians are no longer be able to attest to this improvement activity. We note that this proposed removal was made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of the CY 2020 PFS proposed rule (84 FR 40765). Therefore, this removal is contingent upon finalization of this proposal. We refer readers to section III.K.3.c.(3) of this final rule where we are finalizing our proposal to adopt removal factors.
Comments:	Several commenters supported the removal of this improvement activity. Additional commenters expressed concern that the removal of improvement activities would limit clinician options to choose appropriate improvement activities with similar levels of effort for their practice.
Response:	We appreciate the commenters' support. Since it is no longer feasible for clinicians to attest to this improvement activity due to the TCPI ending on September 28, 2019, we do not believe removal of this improvement activity would limit clinician options.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.

Finalized Improvement Activity	
Activity ID:	N/A – Removed

1/ Transforming Clinical Practice Initiative. Available at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

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